NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry

Guo Ban Fa [2024] No. 53

The people's governments of all provinces, autonomous regions, and municipalities directly under the Central Government; all ministries and commissions of the State Council and all institutions directly under the State Council,

In order to thoroughly implement the important instructions and directives of General Secretary Xi Jinping on the regulation of drugs and medical devices and the development of the pharmaceutical industry, and to comprehensively deepen reforms in drug and medical device regulation to promote the high-quality development of the pharmaceutical industry, the following opinions are proposed with the approval of the State Council.

I. General Requirements

It is required to, taking Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era as the guide, fully implement the spirit of the 20th National Congress of the Communist Party of China (CPC) and the 2nd and 3rd Plenary Sessions of the 20th CPC Central Committee, adhere to the path of scientific, legal, international, and modern regulatory development, coordinate high-quality development and high-level safety, deepen the whole-process reform of drug and medical device regulation, accelerate the construction of a unified national market for drugs and medical devices, and foster a globally competitive innovation ecosystem to promote China's transformation from a major pharmaceutical manufacturer to a pharmaceutical powerhouse and better meet the people's demand for high-quality drugs and medical devices.

By 2027, the legal and regulatory framework for drug and medical device regulation will be more robust, with a regulatory system, regulatory mechanisms, and regulatory approach that are better suited to the needs of pharmaceutical innovation and high-quality industrial development. The quality and efficiency of the review and approval process for innovative drugs and medical devices will be significantly improved. Whole-lifecycle regulation in this field will be strengthened to ensure product safety and quality. A regulatory system fit for pharmaceutical innovation and industrial development will be established. By 2035, China expects to fully ensure the quality, safety, efficacy, and accessibility of drugs and medical devices. The pharmaceutical industry will demonstrate stronger innovation, creativity, and global competitiveness, with its regulatory system modernized.

国务院办公厅关于全面深化药品医疗器械监管改革 促进医药产业高质量发展的意见

国办发〔2024〕53号

各省、自治区、直辖市人民政府，国务院各部委、各直属机构：

为深入贯彻落实习近平总书记关于药品医疗器械监管和医药产业发展的重要指示批示精神，全面深化药品医疗器械监管改革，促进医药产业高质量发展，经国务院同意，现提出以下意见。

一、总体要求

以习近平新时代中国特色社会主义思想为指导，全面贯彻党的二十大和二十届二中、三中全会精神，坚持科学化、法治化、国际化、现代化的监管发展道路，统筹高质量发展和高水平安全，深化药品医疗器械监管全过程改革，加快构建药品医疗器械领域全国统一大市场，打造具有全球竞争力的创新生态，推动我国从制药大国向制药强国跨越，更好满足人民群众对高质量药品医疗器械的需求。

到2027年，药品医疗器械监管法律法规制度更加完善，监管体系、监管机制、监管方式更好适应医药创新和产业高质量发展需求，创新药和医疗器械审评审批质量效率明显提升，全生命周期监管显著加强，质量安全水平全面提高，建成与医药创新和产业发展相适应的监管体系。到2035年，药品医疗器械质量安全、有效、可及得到充分保障，医药产业具有更强的创新创造力和全球竞争力，基本实现监管现代化。

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II. Increase support for innovation in R&D of drugs and medical devices

(I) Improve the review and approval mechanism to fully support major innovations. Following the principles of "early involvement, one enterprise one policy, whole process guidance, and research-review linkage", allocate more review and approval resources to clinically urgently needed key innovative drugs and medical devices. Strengthen communication and provide individualized guidance throughout the entire process of clinical trials, registration submission, inspection and testing, and review and approval. (National Medical Products Administration shall assume relevant responsibilities)

(II) Intensify support for innovation in R&D of traditional Chinese medicine. Refine the theory of traditional Chinese medicine-characteristic evidence-based review system that integrates human use experience and clinical trials. Establish a mechanism for standardized collection and organization of human use experience data by medical institutions. Establish a sound regulatory system for traditional Chinese medicine that conforms to the characteristics of traditional Chinese medicine. Actively support the transformation of prescriptions from renowned veteran traditional Chinese medicine practitioners and traditional Chinese medicine preparations from medical institutions into new traditional Chinese medicine. Encourage the application of new technologies, processes, and dosage forms that are in line with product characteristics to improve marketed traditional Chinese medicine varieties. (National Medical Products Administration shall take the lead; Ministry of Industry and Information Technology, National Health Commission, and National Administration of Traditional Chinese Medicine shall assume responsibilities according to respective duties)

(III) Give full play to the leading role of standards in the innovation of drugs and medical devices. Deepen the implementation of the national action plan for improving drug and medical device standards, and actively promote the research and transformation of standards for new technologies, methods, and tools. Refine the national drug standard database, and publish and timely update the online edition of the Chinese Pharmacopoeia. Optimize the medical device standard system, and research and establish standardization technology organizations for cutting-edge medical devices such as artificial intelligence and medical robots. Enhance the development of standards for traditional Chinese medical devices. (National Medical Products Administration shall take the lead; Ministry of Industry and Information Technology, National Health Commission, State Administration for Market Regulation, and National Administration of Traditional Chinese Medicine shall assume responsibilities according to respective duties)

(IV) Improve policies pertinent to intellectual property protection for drugs and medical devices. For certain drugs approved for marketing, grant categorized regulatory data protection at the time of marketing approval to clinical trial data and other data submitted by registration applicants that are independently obtained and undisclosed. Grant market exclusivity for drugs that meet specified conditions, including those for rare diseases, pediatric drugs, first chemical generic drugs, and exclusive traditional Chinese medicine. Accelerate patent planning for original achievements with regard to drugs and medical devices, and improve patent quality as well as translation and application benefits. (China National Intellectual Property Administration and National Medical Products Administration shall assume responsibilities according to respective duties)

(V) Actively support the promotion and use of innovative drugs and medical devices. Intensify the comprehensive clinical evaluation of innovative drugs, and strengthen the

二、加大对药品医疗器械研发创新的支持力度

（一）完善审评审批机制全力支持重大创新。按照“提前介入、一企一策、全程指导、研审联动”要求，审评审批资源更多向临床急需的重点创新药和医疗器械倾斜，在临床试验、注册申报、核查检验、审评审批等全过程加强沟通交流，提供个性化指导。（国家药监局负责）

（二）加大中药研发创新支持力度。完善中医药理论、人用经验和临床试验相结合的中药特色审评证据体系，建立医疗机构规范收集整理人用经验数据的机制。健全符合中药特点的中药监管体系。积极支持名老中医方、医疗机构中药制剂向中药新药转化。鼓励运用符合产品特点的新技术、新工艺、新剂型改进已上市中药品种。（国家药监局牵头，工业和信息化部、国家卫生健康委、国家中医药局按职责分工负责）

（三）发挥标准对药品医疗器械创新的引领作用。深入推进国家药品医疗器械标准提高行动计划，积极推进新技术、新方法、新工具的标准研究和转化。完善国家药品标准数据库，发布并及时更新网络版中国药典。优化医疗器械标准体系，研究组建人工智能、医用机器人等前沿医疗器械标准化技术组织。加强中医医疗器械标准制定。（国家药监局牵头，工业和信息化部、国家卫生健康委、市场监管总局、国家中医药局按职责分工负责）

（四）完善药品医疗器械知识产权保护相关制度。部分药品获批上市时，对注册申请人提交的自行取得且未披露的试验数据和其他数据，分类别给予一定的数据保护期。对符合条件的罕见病用药品、儿童用药品、首个化学仿制药及独家中药品种给予一定的市场独占期。加快药品医疗器械原创性成果专利布局，提升专利质量和转化运用效益。（国家知识产权局、国家药监局按职责分工负责）

（五）积极支持创新药和医疗器械推广使用。加大创新药临床综合评价力度，加强评价结果分析应用。研究试行以药学和临床价值为

analysis and application of evaluation results. Explore and pilot self-evaluation by MAHs for newly approved drugs based on CMC and clinical values, and optimize online publicity services for newly approved drugs. Adhere to the principle of "guaranteeing basic medical needs" in basic medical insurance, improve the adjustment mechanism for the medical insurance drug catalog, standardize the list of medical consumables and medical service items under medical insurance, and include eligible innovative drugs and medical devices in the medical insurance payment scope in accordance with procedures. Encourage clinical institutions to purchase and use these products. Improve the multi-level medical insurance system and enhance diversified payment capabilities for innovative drugs. Actively disseminate accurate and comprehensive information about innovative drugs and medical devices to the public. (Ministry of Industry and Information Technology, National Health Commission, State Administration for Market Regulation, National Healthcare Security Administration, and National Medical Products Administration shall assume responsibilities according to respective duties)

基础的新上市药品企业自评，优化新上市药品挂网服务。坚持基本医疗保险"保基本"功能定位，完善医保药品目录调整机制，研究规范医保医用耗材目录和医疗服务项目目录，按程序将符合条件的创新药和医疗器械纳入医保支付范围，鼓励医疗机构采购使用。完善多层次医疗保障体系，提高创新药多元支付能力。积极向公众传播准确、全面的创新药和医疗器械信息。（工业和信息化部、国家卫生健康委、市场监管总局、国家医保局、国家药监局按职责分工负责）

III. Improve review/approval quality and efficiency for drugs and medical devices

(VI) Enhance pre-registration guidance for drugs and medical devices. Shorten the communication timeline for clinical trials of clinically urgent innovative drugs. Carry out multi-channel and multi-level communication, effectively organize "cloud class on drug review" and "cloud class on device review", give full play to the roles of evaluation/inspection sub-centers and the central-local linkage mechanism for medical device innovation services, and enhance the publicity and interpretation of registration application rules. (National Medical Products Administration shall assume relevant responsibilities)

(VII) Accelerate the approval of clinically urgently needed drugs and medical devices. Grant priority review to clinically urgently needed cell and gene therapy, overseas marketed drugs, combination vaccines, radiopharmaceuticals, declared substitutes for rare and endangered medicinal materials, as well as high-end medical equipment such as medical robots, brain-computer interface devices, radiotherapy devices, medical imaging devices, innovative traditional Chinese medicine diagnostic and treatment devices, and high-end implantable medical devices. (National Health Commission and National Medical Products Administration shall assume responsibilities according to respective duties)

(VIII) Optimize the review and approval process for clinical trials. Provincial medical products administrations may submit pilot requests for NMPA approval. Once approved, the pilot programs will be conducted in partial regions to optimize clinical trial review and approval process for innovative drugs, shortening the review and approval timeline from 60 working days to 30 working days. Similarly, the clinical trial review and approval timeline for medical devices will also be shortened from 60 working days to 30 working days. Optimize the bioequivalence study filing process. (National Medical Products Administration shall take the lead; provincial people's governments in pilot regions shall provide cooperation)

(IX) Optimize the review and approval for drug supplemental applications. Provincial medical products administrations may submit pilot requests for NMPA approval. Once approved, the pilot programs will be conducted in partial regions to optimize the review and approval of drug supplemental applications, shortening the review and approval timeline from 200 working days to 60 working days for supplemental applications requiring inspection and testing. Optimize drug substance

三、提高药品医疗器械审评审批质效

（六）加强药品医疗器械注册申报前置指导。缩短临床急需创新药临床试验沟通交流等待时限。开展多渠道多层次沟通，办好"药审云课堂"、"器审云课堂"，发挥审评检查分中心和医疗器械创新服务央地联动机制作用，加强对注册申报规则的宣传解读。（国家药监局负责）

（七）加快临床急需药品医疗器械审批上市。对临床急需的细胞与基因治疗药物、境外已上市药品、联合疫苗、放射性药品、珍稀濒危药材替代品的申报品种，以及医用机器人、脑机接口设备、放射性治疗设备、医学影像设备、创新中医诊疗设备等高端医疗装备和高端植介入类医疗器械，予以优先审评审批。（国家卫生健康委、国家药监局按职责分工负责）

（八）优化临床试验审评审批机制。省级药品监管部门提出申请，国家药监局同意后，在部分地区开展优化创新药临床试验审评审批试点，将审评审批时限由60个工作日缩短为30个工作日。医疗器械临床试验审评审批时限由60个工作日缩短为30个工作日。优化生物等效性试验备案机制。（国家药监局牵头，试点地区省级人民政府配合）

（九）优化药品补充申请审评审批。省级药品监管部门提出申请，国家药监局同意后，在部分地区开展优化药品补充申请审评审批程序改革试点，需要核查检验的补充申请审评时限由200个工作日缩短为60个工作日。优化原

management by allowing changes to drug substance registration holders in accordance with the law. (National Medical Products Administration shall take the lead; provincial people's governments in pilot regions shall provide cooperation)

(X) Optimize registration testing for drugs and medical devices. Reduce the required sample quantity per batch from three times the full test amount to two times for registration testing, biologics batch release testing, and customs clearance testing of imported drugs. Establish a green channel for priority testing of innovative drugs and medical devices, and implement testing upon receipt for clinically urgently needed drugs and medical devices. (National Medical Products Administration shall assume relevant responsibilities)

(XI) Accelerate the review and approval of drugs and medical devices for rare diseases. Reduce or waive clinical trials for eligible innovative drugs and medical devices for rare diseases. For drugs for rare diseases, reduce the registration testing requirement from three batches to one batch, and reduce the required sample quantity per batch from three times the full test amount to two times. Coordinate registration inspections and post-marketing inspections for imported drugs for rare diseases based on product risks to shorten the waiting time for overseas inspections. Explore a pilot program allowing specified clinical institutions to import clinically urgently needed drugs and medical devices for rare diseases that have not been registered and marketed in China. Encourage national medical centers to enhance the allocation and utilization of drugs and medical devices for rare diseases. Encourage high-level clinical institutions to independently develop and use diagnostic reagents for rare diseases for which no product of the same kind has been marketed in China. (National Health Commission and National Medical Products Administration shall assume responsibilities according to respective duties)

料药管理，原料药登记主体可依法变更。（国家药监局牵头，试点地区省级人民政府配合）

（十）优化药品医疗器械注册检验。将药品注册检验、生物制品批签发检验和进口药品通关检验每批次用量从全项检验用量的3倍减为2倍。畅通创新药和医疗器械优先检验绿色通道，对临床急需药品医疗器械实行即收即检。（国家药监局负责）

（十一）加快罕见病用药品医疗器械审评审批。对符合条件的罕见病用创新药和医疗器械减免临床试验。将罕见病用药品注册检验批次由3批减为1批，每批次用量从全项检验用量的3倍减为2倍。基于产品风险统筹安排进口罕见病用药品注册核查与上市后检查，缩短境外核查等待时限。探索由特定医疗机构先行进口未在境内注册上市的临床急需罕见病用药品医疗器械。鼓励国家医学中心加大罕见病用药品医疗器械配备和使用力度。鼓励高水平医疗机构自行研制使用国内尚无同品种产品上市的罕见病用诊断试剂。（国家卫生健康委、国家药监局按职责分工负责）

IV. Enhance the compliance of the pharmaceutical industry through efficient and strict regulation

(XII) Advance lot release authorization of biologics (including vaccines). On the basis of adequate risk assessment, gradually expand the scope of testing institutions under provincial drug regulatory authorities and the range of products authorized to implement lot release of biologics (including vaccines). Shorten the lot release timeline for products such as seasonal influenza vaccines to less than 45 working days. (National Medical Products Administration shall take the lead; provincial people's governments in relevant regions shall provide cooperation)

(XIII) Promote the quality improvement of generic drugs. Optimize the review and inspection mechanisms for generic drugs, and intensify pre-approval dynamic inspections based on product risks. Enhance the regulatory of outsourced research and development, contract manufacturing, and post-marketing changes, and provide support for enterprises with high levels of informatization, strong quality assurance, and robust risk prevention and control capabilities to act as contract acceptors. Gradually expand the scope of quality and efficacy consistency evaluations for generic drugs to include dosage forms such as eye drops, patches, sprays, etc. (National Medical Products Administration shall assume relevant responsibilities)

(XIV) Promote information-based manufacturing and testing in pharmaceutical enterprises. Promote the deep integration of new-generation information technologies with the pharmaceutical industry chain, and support the digital and intelligent transformation of drug and medical device manufacturers. Strictly supervise vaccine manufacturers to ensure the full implementation of the informatization requirements in manufacturing and testing processes. Promote the informatization transformation of blood

四、以高效严格监管提升医药产业合规水平

（十二）推进生物制品（疫苗）批签发授权。在充分评估风险基础上，逐步扩大授权实施生物制品（疫苗）批签发的省级药品监管部门检验检测机构和品种范围。季节性流感疫苗等品种的批签发时限缩短至45个工作日以内。（国家药监局牵头，有关地区省级人民政府配合）

（十三）促进仿制药质量提升。优化仿制药审评、核查工作机制，基于产品风险加大批准前动态检查力度。加强对委托研发、受托生产和上市后变更的监管，支持信息化水平高、质量保证和风险防控能力强的企业接受委托。将仿制药质量和疗效一致性评价逐步向滴眼剂、贴剂、喷雾剂等剂型拓展。（国家药监局负责）

（十四）推动医药企业生产检验过程信息化。推动新一代信息技术与医药产业链深度融合，支持药品医疗器械生产企业数智化转型。严格监督疫苗生产企业全面落实生产检验过程

product manufacturing in batches, and promote the establishment of an informatization management system for blood products covering the entire process from plasma collection and factory entry to manufacturing and testing. (Ministry of Industry and Information Technology, National Health Commission, and National Medical Products Administration shall assume responsibilities according to respective duties)

(XV) Enhance the efficiency of regulatory inspections for drugs and medical devices. Strengthen quality and safety warning education for enterprises, and urge them to comprehensively improve their quality management systems. Reasonably establish the inspection frequency based on risk levels of enterprises and products, and reduce repetitive inspections. Encourage national and provincial medical products administrations to jointly conduct registration on-site inspections and good manufacturing practice compliance inspections involving manufacturing enterprises. Conduct combined inspections for class II or III medical device manufacturers that also produce class I medical devices. (National Medical Products Administration shall assume relevant responsibilities)

(XVI) Strengthen pharmacovigilance for innovative drugs and medical devices. Guide and urge MAHs for innovative drugs to establish and refine pharmacovigilance systems, actively monitor, report, and analyze adverse reactions, and continuously conduct post-marketing studies for innovative drugs. Improve the monitoring platform for adverse drug reactions and medical device adverse events based on the risk characteristics of innovative drugs and medical devices. Strengthen post-marketing active monitoring of innovative drugs and medical devices. (National Health Commission and National Medical Products Administration shall assume responsibilities according to respective duties)

(XVII) Improve the regulatory quality and efficiency of new business forms in pharmaceutical circulation. Establish a joint governance alliance to address safety risks in the online sales of drugs and medical devices, and clarify the responsibilities of third-party online transaction platforms. Support wholesalers to effectively integrate warehousing and transportation resources, and build a multi-warehouse collaborative logistics management model. Optimize the licensing processes and increase the retail chain rate. Allow cross-provincial sales of traditional Chinese medicine decoction pieces processed according to provincial processing specifications, as well as direct cross-provincial sales of traditional Chinese medicine formula granules manufactured in accordance with national drug specifications. (National Medical Products Administration shall take the lead; Ministry of Commerce, National Health Commission, State Administration for Market Regulation, and National Administration of Traditional Chinese Medicine shall assume responsibilities according to respective duties)

V. Support the pharmaceutical industry in expanding opening-up and international cooperation

(XVIII) Deepen the adoption and implementation of international general regulatory rules. Continue to promote the alignment of drug review technical requirements with the rules of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Provide support for drug clinical trial institutions to participate in early clinical research and development of innovative drugs, and facilitate the conduct of international multi-center clinical trials. Promote the concurrent research and development, application, evaluation, and marketing of global drugs in China. Actively promote the adoption and implementation of technical guidelines from the International Medical Device Regulators Forum and the Global

信息化要求。分批推进血液制品生产信息化改造，推动建立覆盖从采浆、入厂到生产、检验全过程的血液制品信息化管理体系。（工业和信息化部、国家卫生健康委、国家药监局按职责分工负责）

（十五）提高药品医疗器械监督检查效率。强化面向企业的质量安全警示教育，督促企业全面完善质量管理体系。根据企业和产品风险等级合理确定检查频次，减少重复检查。鼓励国家与省级药品监管部门协同开展涉及生产企业的注册现场检查与生产质量管理规范符合性检查。对同时生产第一类医疗器械的第二类、第三类医疗器械生产企业，开展合并检查。（国家药监局负责）

（十六）强化创新药和医疗器械警戒工作。指导督促创新药上市许可持有人建立完善药物警戒体系，主动监测、报告和分析不良反应，持续开展创新药上市后研究。基于创新药和医疗器械风险特点完善药品不良反应和医疗器械不良事件监测平台。加强创新药和医疗器械上市后主动监测。（国家卫生健康委、国家药监局按职责分工负责）

（十七）提升医药流通新业态监管质效。建立药品医疗器械网络销售安全风险共治联盟，压实网络交易第三方平台责任。支持批发企业有效整合仓储资源和运输资源，构建多仓协同物流管理模式。优化许可流程，提高零售连锁率。按照省级炮制规范炮制的中药饮片可按规定跨省销售，按照国家药品标准生产的中药配方颗粒可直接跨省销售。（国家药监局牵头，商务部、国家卫生健康委、市场监管总局、国家中医药局按职责分工负责）

五、支持医药产业扩大对外开放合作

（十八）深入推进国际通用监管规则转化实施。持续推动药品审评技术要求与国际人用药品技术协调会规则协调一致，支持药物临床试验机构参与创新药物早期临床研发，支持开展国际多中心临床试验，促进全球药物在我国同步研发、同步申报、同步审评、同步上市。积极推进国际医疗器械监管机构论坛、全球医

Harmonization Working Party towards Medical Device Harmonization in China. (National Health Commission and National Medical Products Administration shall assume responsibilities according to respective duties)

(XIX) Explore segmented production models for biologics. Provincial medical products administrations may submit pilot requests for National Medical Products Administration approval. Once approved, the pilot programs will be conducted in partial regions for biologics with special requirements for manufacturing processes, facilities, and equipment. Priority will be given to segmented production of antibody-drug conjugates, combined polyvalent vaccines, etc. Provide support for qualified overseas drug MAHs to carry out cross-border segmented production in the form of self-built manufacturing capacity or contract manufacturing under unified drug quality management systems. (National Medical Products Administration shall take the lead; provincial people's governments in pilot regions shall provide cooperation)

(XX) Optimize import approval of drugs and medical devices. Simplify the review and approval of traditional oral Chinese patent medicines that have been marketed in Hong Kong and Macao. Optimize the management of imported medicinal materials, and expand the import of overseas high-quality medicinal material resources. For overseas-marketed drugs that have obtained drug approval certificates in China, allow the import and sale of pre-approval commercial-scale batches that meet requirements. Optimize the review and approval process for localizing the manufacturing of overseas manufactured drugs and medical devices that have been marketed in China, and provide support for foreign-invested enterprises in localizing the manufacture of original drugs and high-end medical equipment. (National Medical Products Administration shall assume relevant responsibilities)

(XXI) Support the export trade of drugs and medical devices. Accelerate and promote inclusion into the international Pharmaceutical Inspection Co-operation Scheme. Expand the scope of export sales certificate issuance to include all drugs and medical devices manufactured by qualified manufacturers in accordance with good manufacturing practices. Strengthen international exchanges and cooperation with regard to traditional Chinese medicine resources, actively promote and exchange international regulatory policies, and support the overseas registration and marketing of traditional Chinese medicine with clinical superiorities. (Ministry of Commerce, National Administration of Traditional Chinese Medicine, and National Medical Products Administration shall assume responsibilities according to respective duties)

疗器械法规协调会技术指南在我国转化实施。（国家卫生健康委、国家药监局按职责分工负责）

（十九）探索生物制品分段生产模式。省级药品监管部门提出申请，国家药监局同意后，在部分地区开展生产工艺、设施设备有特殊要求的生物制品分段生产试点，率先推进抗体偶联药物、多联多价疫苗等分段生产。支持符合条件的境外药品上市许可持有人在统一的药品质量管理体系下，以自建产能或者委托生产形式开展跨境分段生产。（国家药监局牵头，试点地区省级人民政府配合）

（二十）优化药品医疗器械进口审批。简化香港、澳门已上市传统口服中成药审评审批。优化进口药材管理，扩大境外优质药材资源进口。境外已上市药品在取得我国药品批准证明文件后，对符合要求的获批前商业规模批次产品，允许进口销售。优化已在境内上市的境外生产药品医疗器械转移至境内生产的审评审批流程，支持外商投资企业将原研药品和高端医疗装备等引进境内生产。（国家药监局负责）

（二十一）支持药品医疗器械出口贸易。加快推进加入国际药品检查合作计划。将出具出口销售证明的范围拓展到所有具备资质的企业按照生产质量管理规范生产的药品医疗器械。加强中药资源国际交流合作，积极开展国际监管政策宣贯和交流，支持具有临床优势的中药在境外注册上市。（商务部、国家中医药局、国家药监局按职责分工负责）

VI. Build a regulatory system adapted to the needs of industrial development and safety

(XXII) Continuously strengthen the building of the regulatory capacity. Optimize the setup of regulatory technical support institutions, strengthen the development of professional teams, and enrich the pool of high-quality technical expertise. Gradually assign more responsibilities to evaluation/inspection sub-centers whose capabilities meet standards, expand the scope of evaluated products and inspected enterprises, and steadily develop evaluation and inspection capabilities tailored to regional industrial characteristics. Promote the capacity evaluation for medical device evaluation institutions and reviewers under provincial medical products administrations. Encourage each region to improve local regulatory systems and mechanisms and strengthen team capacity building in line with the actual development of the pharmaceutical industry. Encourage provincial drug regulatory

六、构建适应产业发展和安全需要的监管体系

（二十二）持续加强监管能力建设。优化监管技术支撑机构设置，加强专业化队伍建设，充实高素质专业化技术力量。逐步赋予能力达标的审评检查分中心更多职责，扩大审评产品和检查企业范围，稳步发展与区域产业特点相适应的审评检查能力。推进省级药品监管部门医疗器械审评机构和审评人员能力评价。鼓励各地结合医药产业发展实际，完善地方监

authorities with the capacity to actively promote pilot reforms and increase the scope of drug and medical device evaluation work. (National Medical Products Administration shall take the lead; Ministry of Human Resources and Social Security and provincial people's governments shall assume responsibilities according to respective duties)

(XXIII) Vigorously developing drug regulatory sciences. With the national key laboratories for drug regulatory sciences as the leading force, strengthen the construction of innovation research bases for drug regulatory sciences. Deploy and advance key tasks in drug regulatory science and technology, improve mechanisms for the transformation of research outcomes, and enhance incentives for scientific research personnel. Accelerate the development of new tools, standards, and methods to support regulatory decision-making. (Ministry of Science and Technology and National Medical Products Administration shall assume responsibilities according to respective duties)

(XXIV) Strengthen regulatory informatization. Promote the online processing of drug and medical device regulatory government services, covering the entire process from application and acceptance to review and certificate issuance. Improve the national drug intelligence regulatory platform, strengthen the data collection and governance of product archives and credit records, and explore the implementation of comprehensive regulation. Promote the implementation and application of unique medical device identification in promoting the coordinated development and governance of healthcare services, health insurance, and the pharmaceutical industry. Strengthen the construction of a full-chain drug traceability system, enforce corporate accountability, and gradually achieve traceability throughout the process of manufacturing, distribution, and use. (National Medical Products Administration shall take the lead; National Development and Reform Commission, Ministry of Industry and Information Technology, National Health Commission, and National Healthcare Security Administration shall assume responsibilities according to respective duties)

All regions and relevant departments shall adhere to and strengthen the integration of the Party leadership into all aspects and throughout the entire process of deepening the reform of drug and medical device regulation, fully recognize the importance of advancing high-quality development of the pharmaceutical industry through these reforms, and implement the opinions herein in accordance with the "four strictest" requirements. Relevant departments shall strengthen collaboration and cooperation, consolidate efforts, enhance funding and talent support, promote the implementation and refinement of each task, and ensure the effective implementation of each policy and measure. In case of major issues, instructions shall be timely requested from the Party Central Committee and the State Council.

General Office of the State Council
December 30, 2024

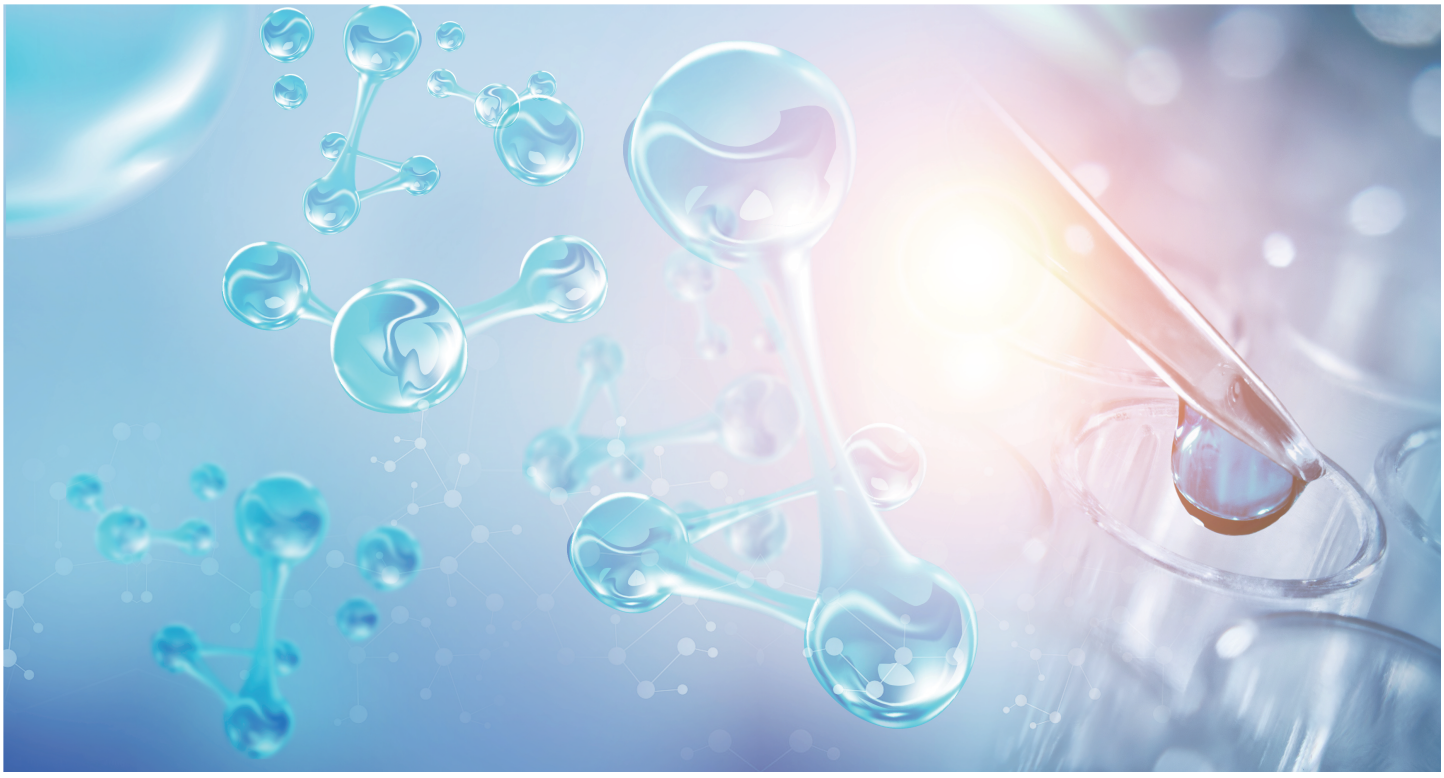
管体制机制，加强队伍能力建设。鼓励有条件的省级药品监管部门积极推进改革试点，开展更多药品医疗器械审评等工作。（国家药监局牵头，人力资源社会保障部和各省级人民政府按职责分工负责）

（二十三）大力发展药品监管科学。以药品监管科学全国重点实验室为龙头，加强药品监管科学创新研究基地建设。部署推进药品监管科学技术攻关任务，完善成果转化和科研人员激励机制，加快开发支持监管决策的新工具、新标准、新方法。（科技部、国家药监局按职责分工负责）

（二十四）加强监管信息化建设。推动药品医疗器械监管政务服务事项从申请、受理、审查到制证等全环节全流程在线办理。完善国家药品智慧监管平台，强化品种档案和信用档案的数据汇集与治理，探索开展穿透式监管。推动医疗器械唯一标识在促进医疗、医保、医药协同发展和治理中的实施应用。加强全链条药品追溯体系建设，落实企业主体责任，逐步实现生产、流通、使用全过程可追溯。（国家药监局牵头，国家发展改革委、工业和信息化部、国家卫生健康委、国家医保局按职责分工负责）

各地区、各有关部门要把坚持和加强党的领导贯穿于深化药品医疗器械监管改革的各方面和全过程，充分认识以改革促进医药产业高质量发展的重要意义，按照“四个最严”要求，抓好本意见的贯彻落实。有关部门要加强协同配合，凝聚工作合力，强化经费和人才保障，推动各项任务落实落细，确保各项政策措施落地见效。重大事项及时向党中央、国务院请示报告。

国务院办公厅
2024年12月30日



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