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Headline

NMPA holds meeting to review QMS in vaccine regulation, pharmaceutical manufacturing inspection

The National Medical Products Administration (NMPA) held a meeting on June 9 to conduct the 2024 annual review of the quality management system (QMS) in vaccine regulation and pharmaceutical manufacturing inspection. NMPA Commissioner Li Li chaired the meeting and fully affirmed the suitability, adequacy, and effectiveness of the NMPA's QMS in these two areas.

The establishment and operation of the QMS in vaccine regulation and pharmaceutical manufacturing inspection represents a major effort to meet the assessment requirements of the World Health Organization's National Regulatory Authority (NRA) for vaccines and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as well as to enhance the national capabilities in vaccine regulation and pharmaceutical manufacturing inspection. The NMPA attaches great significance to the development of the vaccine regulatory QMS, and is dedicated to promoting the regular and standardized operation of the system to continuously enhance the efficiency of vaccine regulatory work by adhering to goal-oriented and problem-focused approaches.

At the meeting, the Department of Policies and Regulations and the Department of Drug Regulation respectively reported on the overall situation of the development and operation of the QMS in vaccine regulation and pharmaceutical manufacturing inspection in 2024, highlighted identified problems and follow-up rectifications, and offered suggestions for system improvement. The meeting also reviewed the annual performance of the system in the departments of comprehensive affairs, planning and finance affairs, policies and regulations, drug registration, drug regulation and human resources.

Li said that by further enhancing the effective operation of the vaccine regulatory QMS and coordinating the smooth implementation of the QMS in pharmaceutical manufacturing inspection, the NMPA has fully leveraged the QMS' role in whole-lifecycle monitoring, evaluation and inspection, and continuously improved drug regulation. The NMPA's vaccine QMS and pharmaceutical manufacturing inspection QMS are appropriate, adequate and effective, with remarkable results achieved, he noted.

He said that a team of pharmaceutical inspectors has been developed through management on the basis of classification and categories and high-level training to conform to the international standards, while relevant departments have advanced whole-lifecycle quality management, and held regular risk consultations and efficient internal audits to ensure compliant and well-organized drug regulation.

He further emphasized the need to enhance nationwide coordination and cooperation in establishing and operating QMS standards. He also stressed the importance of conducting in-depth research and promoting robust drug regulatory capabilities based on sound QMS in line with international standards, so as to contribute to the high-quality development of China's pharmaceutical industry.

(2025-06-09)

头条

国家药监局开展疫苗监管及药品生产检查质量管理体系管理评审

6月9日，国家药监局开展2024年度疫苗监管及药品生产检查质量管理体系（疫苗QMS及药品生产检查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QMS及药品生产检查QMS的适宜性、充分性和有效性予以充分肯定。

建立运行疫苗QMS及药品生产检查QMS是适应世界卫生组织（WHO）疫苗国家监管体系（疫苗NRA）评估及药品检查合作计划（PIC/S）要求，推动提升国家疫苗监管、药品生产检查能力水平的重要工作。国家药监局高度重视质量管理体系建设，坚持目标导向和问题导向，推动体系常态化、规范化运行，不断提升工作效能。

管理评审中，政法司、药品监管司分别汇报了2024年度局机关疫苗QMS、药品生产检查QMS的建设运行整体情况，并报告了发现问题、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。

李利指出，国家药监局通过继续深化疫苗QMS有效运行，协调推进药品生产检查QMS平稳起步，充分发挥质量管理体系全过程监测评查作用，持续完善药品监管相关工作，国家药监局机关疫苗QMS及药品生产检查QMS适宜、充分、有效，工作取得明显成效。通过药品检查员分级分类管理，高水平开展药品检查员培训，培养一批具有国际水平的骨干检查员，监管人员能力不断增强。相关司局认真贯彻落实质量管理理念，坚持全过程质量管理，定期开展风险会商，持续高效开展内审工作，推动药品监管工作更加合规有序。

李利强调，要树立全国"一盘棋"意识，在质量管理体系建设标准、运行方面形成联动；要深入开展研究，对照国际标准，以良好的监管质量管理体系推动药品监管能力提升，促进中国医药产业高质量发展。

（2025-06-09）

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Drugs

Policy Interpretation of *Provisions on the Experimental Research of Narcotic Drugs and Psychotropic Substances*

I. What requirements does the *Provisions* set forth for the safety management of experimental research involving narcotic drugs and psychotropic substances (hereinafter referred to as narcotic and psychotropic drugs)?

To strengthen the safety management of experimental research involving narcotic and psychotropic drugs, the *Provisions* propose requirements from multiple aspects, including safety management systems and facilities and equipment, entrusted research management, management of experimental researchers, and management of narcotic and psychotropic drugs and active substances. For example, the approval holder is required to assess the research capability and the safety management capability regarding narcotic and psychotropic drugs of third-party institutions entrusted to conduct research; the approval holder and co-development entities are required to strictly manage the active substances generated during experimental research. The approval holder and co-development entities should manage the entire experimental research process in accordance with the *Provisions* to prevent narcotic and psychotropic drugs, active substances, and related synthesis technologies from flowing into illegal channels.

II. The *Provisions* require that the approval holder and co-development entities complete the research within the validity period of the experimental research project approval for narcotic and psychotropic drugs and submit a drug registration application. How should "drug registration application" be understood?

"Drug registration application" refers to submitting an application for drug clinical trials (or completing the bioequivalence trial filing) in accordance with statutory procedures and relevant requirements; for drugs meeting the conditions for exemption from clinical trials, it refers to submitting an application for marketing authorization.

III. How should experimental research project approvals obtained prior to the implementation of the Provisions be managed?

The *Provisions* extend the validity period of experimental research project approvals from 3 years to 5 years, and except for innovative drugs, approvals for other varieties are generally not subject to extension. For approvals obtained prior to the implementation of the *Provisions* and still within their validity period, the approval holder may apply for a one-time extension. The National Medical Products Administration (NMPA) will decide whether to approve the extension in accordance with prescribed procedures, considering the progress of experimental research and other factors.

IV. How should "varieties not yet listed in the narcotic drugs and psychotropic substances catalog but with dependence potential" be understood?

It refers to varieties indicated in relevant literature as having dependence potential, varieties already controlled as narcotic and psychotropic drugs overseas, varieties structurally similar or sharing the same targets as narcotic and psychotropic drugs, and varieties demonstrating dependence in animal experiments.

If dependence is discovered during clinical trials of the studied variety, the approval holder should promptly submit a project application for experimental research

V. Under what special circumstances should an experimental research application be submitted for varieties newly listed in the catalog of the narcotic and psychotropic drugs?

From the date on which the national announcement adjusting the catalog of narcotic and psychotropic drugs is issued, entities that have already initiated experimental research involving newly listed varieties, obtained approval to conduct clinical trials (or completed the filing for bioequivalence trials), or whose product is undergoing drug registration review and approval but has not yet received a marketing authorization for the relevant variety, should promptly submit an

药品

《麻醉药品和精神药品实验研究管理规定》政策解读

一、《规定》对麻醉药品和精神药品（以下简称麻精药品）实验研究安全管理提出了哪些要求?

为加强麻精药品实验研究安全管理，《规定》从安全管理制度和设施设备、委托研究管理、实验研究人员管理、麻精药品和活性物质管理等多方面提出要求。例如，要求批件持有人对受托开展研究的第三方机构的研究能力和麻精药品安全管理能力进行评估；要求批件持有人和联合研制单位对实验研究产生的活性物质严格管理等。批件持有人和联合研制单位应当按照《规定》做好实验研究全过程的管理，防止麻精药品、活性物质和相关合成技术流入非法渠道。

二、《规定》要求，批件持有人和联合研制单位在麻精药品实验研究立项批件有效期内完成研究，提出药品注册申请。"药品注册申请"如何理解?

"药品注册申请"是指依照法定程序和相关要求提出药物临床试验申请（或完成生物等效性试验备案）；符合豁免药物临床试验条件的提出药品上市许可申请。

三、《规定》施行前取得的实验研究立项批件如何管理?

《规定》将实验研究立项批件有效期由3年调整为5年，且除创新药以外品种的批件原则上不予延期。《规定》施行前取得的、尚在有效期内的批件，批件持有人可以申请延期1次。国家药监局将结合实验研究进展等情况，并按照规定程序作出是否批准延期的决定。

四、"尚未列入麻醉药品和精神药品目录，但具有依赖性潜力的品种"如何理解?

在相关文献中提示具有依赖性的品种、在境外已列入麻精药品管制的品种、与麻精药品结构类似或具有相同靶点的品种，以及在动物实验中显示具有依赖性的品种。

临床试验过程中发现所研究品种具有依赖性，批件持有人也应及时提出实验研究立项申请。

五、对新列入麻精药品目录品种，有哪些特殊情况应提出实验研究申请?

自国家发布调整麻精药品目录公告之日起，已开展新增列管品种的实验研究、已获准开展临床试验（或完成生物等效性试验备案）、已在药品注册审评审批过程中但尚未取得相应品种上市许可的单位，应及时按照《规定》向国家药监局提出相关品种的实验研究立项申请。

experimental research project application for the variety in accordance with the *Provisions*.

VI. How is the term "Principal Investigator" defined in the *Provisions*?

"Principal Investigator" refers to researchers who possess knowledge of the preparation methods of the experimental research variety, as well as the persons in charge of the respective levels of research work for the variety.

VII. How should "corresponding or higher level of control" be understood?

The *Provisions* specify that the levels of control over narcotic and psychotropic drugs, from highest to lowest, are ranked as narcotic drugs, Class I psychotropic substances, and Class II psychotropic substances. For experimental research on varieties other than innovative drugs, at least one of the applicant or co-development entities should be a designated manufacturer holding the corresponding control level or a higher control level qualification for the proposed research variety. For example, if the proposed research variety is a Class II psychotropic substance, at least one enterprise among the applicant or co-development entities should have obtained designated manufacturing qualification for Class II psychotropic substances, or at least one enterprise should hold designated manufacturing qualification for Class I psychotropic substances, or at least one enterprise should hold designated manufacturing qualification for narcotic drugs;if the proposed research variety is a Class I psychotropic substance, at least one enterprise among the applicant or co-development entities should have obtained designated manufacturing qualification for Class I psychotropic substances, or at least one enterprise should have designated manufacturing qualification for narcotic drugs; if the proposed research variety is a narcotic drug, at least one enterprise among the applicant or co-development entities should have obtained designated manufacturing qualification for narcotic drugs.

VIII. What is the difference between co-development entities and entrusted third-party institutions?

Co-development entities refer to enterprises or drug R&D institutions that jointly submit the narcotic and psychotropic drugs experimental research project application with the applicant and conduct experimental research. If the approval holder intends to conduct experimental research jointly with other enterprises or drug R&D institutions, an application to add co-development entities should be submitted to the NMPA, and joint research may proceed only after approval; if the approval holder intends to change co-development entities, an application should also be submitted to the NMPA.

The entrusted third-party institutions refer to institutions with corresponding qualifications entrusted by the approval holder to carry out specific testing items or pharmacological and toxicological studies, particularly those involving high-cost and low-frequency use of specialized analytical equipment. The approval holder should supervise the entrusted third-party institutions.

(May 30, 2025)

六、《规定》中"主要研究人员"是指哪些人员?

"主要研究人员"指掌握实验研究品种制备方法的研究人员以及承担该品种研究工作的各级研究负责人。

七、"相应管制级别或更高管制级别"如何理解?

《规定》明确麻精药品管制级别由高到低依次为麻醉药品、第一类精神药品、第二类精神药品。开展创新药以外品种实验研究的，申请人和联合研制单位中应当至少有1家为拟研发品种相应管制级别或更高管制级别的定点生产企业。例如，拟研发品种为第二类精神药品，申请人和联合研制单位中应当至少有1家企业已取得第二类精神药品定点生产资质，或至少有1家企业已取得第一类精神药品定点生产资质，或至少有1家企业已取得麻醉药品定点生产资质；拟研发品种为第一类精神药品，申请人和联合研制单位中应当至少有1家企业已取得第一类精神药品定点生产资质，或至少有1家企业已取得麻醉药品定点生产资质；拟研发品种为麻醉药品，申请人和联合研制单位中应当至少有1家企业已取得麻醉药品的定点生产资质。

八、联合研制单位和接受委托的第三方机构有什么区别?

联合研制单位是指与申请人共同提出麻精药品实验研究立项申请并开展实验研究的企业或药品研制机构。如批件持有人拟与其它企业或药品研制机构共同开展实验研究，应向国家药监局提出增加联合研制单位申请，获准后方可共同开展实验研究；如批件持有人拟变更联合研制单位，也应向国家药监局提出申请。

接受委托的第三方机构是指接受批件持有人委托，开展涉及使用成本高昂、使用频次较少的专业检验设备的个别检验项目或药理毒理学研究的具有相应资质的机构。批件持有人应对接受委托的第三方机构进行监督。

(2025-05-30)

Medical device

Policy Interpretation of the *Quality Management Specifications for Online Sales of Medical Devices*

I. Background of the formulation of the *Quality Management Specifications for Online Sales of Medical Devices* (hereinafter referred to as the *Specifications*)

With the rapid development of e-commerce, the online medical device sales market in China has experienced explosive growth in recent years. According to statistics, from 2018 to the present, the number of medical device distributors engaged in online sales has increased from 8,717 to over 360,000, while the number of third-party platform enterprises has grown from 77 to 851.

The NMPA has always attached great importance to the quality and safety of medical device online sales, continuously improving

医疗器械

《医疗器械网络销售质量管理规范》政策解读

一、《医疗器械网络销售质量管理规范》(以下简称《规范》)的制定背景

随着电子商务快速发展，近年来，我国医疗器械网络销售市场迎来爆发式增长。据统计，从2018年至今，从事网络销售的医疗器械经营企业由8717家增至36万余家，第三方平台企业由77家增长至851家。

the relevant regulations for online sales of medical devices. The relevant provisions on online sales have been incorporated into the newly revised *Regulations for the Supervision and Administration of Medical Devices*, and the *Measures on the Supervision and Administration of Online Sales of Medical Devices* have been issued and implemented to promote the healthy and orderly development of the online medical device market.

With the continuous deepening of regulatory efforts, local drug regulatory authorities and enterprises have reflected that there is a lack of unified normative guidance in practice, and there is an urgent need to formulate practical, scientific, effective, and operable normative requirements to guide enterprises in better fulfilling their principal responsibilities and promoting the healthy development of the industry.

II. Overall Approach and Main Content of the *Specifications*

As an important normative document to guide the quality management as well as supervision and administration of online sales of medical devices, the *Specifications* focus on four key principles in its overall approach: First, upholding and implementing the requirements of laws and regulations. The *Specifications* were drafted in accordance with relevant laws, administrative regulations, and departmental rules, including the *E-Commerce Law of the People's Republic of China,* the *Regulations for the Supervision and Administration of Medical Devices,* the *Measures on the Supervision and Administration of Online Sales of Medical Devices,* and the *Provisions for Supervision and Administration of Medical Device Distribution.* Second, ensuring the fulfillment of the primary responsibilities by enterprises. By refining management norms, the *Specifications* specify that the online sales operators and platform operators of medical devices should earnestly fulfill their social responsibilities and obligations, proactively strengthen quality risk prevention and control, and ensure the quality and safety of medical devices sold through online channels. Third, summarizing and building on regulatory practice and experience. The content of the *Specifications* is closely aligned with the newly revised *Good Supply Practice for Medical Devices* and incorporates beneficial practices and experiences from local regulatory authorities in the supervision and management of online sales of medical devices, proposing effective and actionable quality management requirements for online sales. Fourth, extensively listening to and responding to industry demands. The drafting process involved broad consultation with stakeholders in the industry to better understand the challenges encountered in online sales quality management. It aimed to proactively identify and address the urgent needs and expectations of enterprises, promote innovative regulatory approaches, and implement the "Streamline Administration, Delegate Power, Strengthen Regulation and Improve Services" reform. While safeguarding quality and safety, the Specifications seek to meaningfully respond to industry concerns, resolve pain points, and unleash market innovation vitality.

The *Specifications* consist of four chapters and fifty articles, divided into General Provisions, Quality Management for Online Sales Operators, Quality Management for E-commerce Platform Operators, and Supplementary Provisions. The Specifications establish the basic requirements that online sales operators and e-commerce platform operators should, in accordance with the provisions herein, establish and improve a quality management system suited to the online sales of medical devices and ensure its effective operation.

III. Relationship between the *Specifications* and the *Good Supply Practice for Medical Devices*

The *Quality Management Specifications for Online Sales of Medical Devices* and the *Good Supply Practice for Medical Devices* are complementary in content and parallel in legal status, serving as two normative documents at the same regulatory level.

Online sales of medical devices represent a specialized business model under the broader category of medical device distribution. Enterprises engaged in such activities must first comply with applicable laws, administrative regulations, and normative documents, including the *Regulations for the Supervision and Administration of Medical Devices,* the *Provisions for Supervision and Administration of Medical Device Distribution,* and the *Good Supply Practice for Medical Devices.*

国家药品监督管理局一直高度重视医疗器械网络销售质量安全，不断完善医疗器械网络销售监管法规，将网络销售有关规定纳入新修订《医疗器械监督管理条例》，颁布实施了《医疗器械网络销售监督管理办法》，推动医疗器械网络销售市场健康有序发展。

随着监管工作的不断深入，地方药品监管部门和企业反映，在实践工作中缺乏统一规范指导，亟待制定切实科学有效、可操作的规范要求，指导企业更好地落实主体责任，促进行业规范健康发展。

二、《规范》的总体思路和主要内容

作为指导医疗器械网络销售质量管理与监督管理的重要规范性文件，《规范》在制定的总体思路上，主要把握了四项原则：一是坚持贯彻落实法律法规要求。依据《中华人民共和国电子商务法》《医疗器械监督管理条例》《医疗器械网络销售监督管理办法》《医疗器械经营监督管理办法》等相关法律、法规和部门规章，起草相关内容。二是坚持落实企业主体责任。通过细化管理规范要求，明确医疗器械网络销售经营者和平台经营者应切实履行社会责任和义务，主动加强质量风险防控，保障网络销售医疗器械产品质量安全。三是总结发扬监管实践经验。《规范》在内容上与新修订的《医疗器械经营质量管理规范》充分衔接，同时吸收地方监管部门在医疗器械网络销售监督管理方面的有益实践和经验做法，提出行之有效的网络销售质量管理要求内容。四是广泛听取与回应行业诉求。广泛听取行业内各方在医疗器械网络销售质量管理中遇到的问题，主动了解企业所急所需所盼，创新监管理念和方式，落实"放管服"改革思路，在保障质量安全的前提下，倾心回应行业诉求，解决行业难点，促进释放市场创新活力。

《规范》共四章五十条，分为总则、网络销售经营者质量管理、电商平台经营者质量管理和附则。提出了网络销售经营者和电商平台经营者应当按照本规范要求，建立健全与网络销售医疗器械相适应的质量管理体系并保证其有效运行等基本要求。

三、《规范》与《医疗器械经营质量管理规范》之间的关系

《医疗器械网络销售质量管理规范》与《医疗器械经营质量管理规范》是在内容上互为补充，法律层级上互相并列的两个规范性文件。

医疗器械网络销售是医疗器械经营大概念下的特殊业态，相关企业开展网络销售活动的前提是要符合《医疗器械监督管理条例》《医疗器械经营监督管理办法》《医疗器械经营质量管理规范》等法规、规章和规范等规定要求。《医疗器械监督管理条例》第四十六条明确，从事医疗器械网络销售的，应当是医疗器械注

Article 46 of the *Regulations for the Supervision and Administration of Medical Devices* clearly stipulates that entities engaging in the online sales of medical devices should be either medical device registrants, filers, or licensed medical device distributors. Therefore, the *Specifications* propose quality management requirements for various aspects of online sales operators, such as the responsibilities of quality management departments, staffing, quality system documentation, incoming inspection, and sales/purchase records based on the requirements of the *Good Supply Practice for Medical Devices,* while taking into account the characteristics of online distribution.

IV. In what aspects does the *Specifications* further reinforce the responsibilities of online sales operators?

The *Specifications* strictly implement the provisions and requirements of laws, regulations, and normative documents, including the *E-Commerce Law of the People's Republic of China,* the *Regulations for the Supervision and Administration of Medical Devices,* the *Provisions for Supervision and Administration of Medical Device Distribution,* and the *Measures on the Supervision and Administration of Online Sales of Medical Devices.* First, establish a quality management system for online sales of medical devices. The Specifications guide online sales operators to establish and improve a quality management system suited to online sales of medical devices, including refining the responsibilities of quality management departments, enriching the content of personnel training, improving the formulation of system documents, and clarifying requirements for system self-inspections. Second, strengthen guidelines for quality management of online sales. The Specifications guide online sales operators to standardize quality management practices for online sales, including legally displaying enterprise qualification information and product information, maintaining complete online sales records and relevant supporting documents, and taking effective measures to ensure product quality and safety during transportation. Third, promote online sales operators to strengthen risk management. The Specifications require that, upon identifying any product quality issues or potential safety risks, online medical device sales operators should take risk control measures in accordance with the law, such as suspending the display of product information or suspending sales, when quality issues or potential safety hazards are identified in their products.

V. What are the requirements of the *Specifications* regarding the public disclosure of business entity information?

Article 15 of the *E-Commerce Law of the People's Republic of China* clearly requires that e-commerce operators prominently and continuously disclose their business license information and administrative licensing information related to their business operations on the homepage of their platforms. The *Specifications* implement the registrant and filing entity system for medical devices and set forth public disclosure requirements for enterprise entity information under three distinct circumstances: For medical device distributors that have obtained a distribution license or completed filing procedures, they should publicly display their Medical Device Business License or Class II Medical Device Distribution Filing Certificate; For medical device registrants that have obtained a manufacturing license, they should publicly display their Medical Device Manufacturing License; For medical device registrants that outsource production to other enterprises, they should publicly display the Medical Device Registration Certificate. The relevant certificates and credentials may be disclosed using images or links to the corresponding electronic certificates, and certificate or credential numbers should be displayed in text format.

VI. Are there any special requirements for the sale of medical devices, such as contact lenses and hearing aids, that require specific fitting?

Medical devices such as contact lenses and hearing aids should undergo professional fitting, adjustment, or trial use prior to being used. The fitting process should ensure that the product meets the individual needs of the user, thereby minimizing discomfort and potential risks during use.

According to Article 17 of the *E-commerce Law of the People's Republic of China,* e-commerce operators should

册人、备案人或者医疗器械经营企业。因此，《规范》对网络销售经营者的质量管理机构职责、人员、质量管理体系文件、进货查验与购销记录等多个质量管理环节，均基于《医疗器械经营质量管理规范》的规定，并结合网络销售的特点，提出质量管理要求。

四、《规范》从哪些方面进一步压实网络销售经营者责任?

《规范》严格落实《中华人民共和国电子商务法》《医疗器械监督管理条例》《医疗器械经营监督管理办法》《医疗器械网络销售监督管理办法》等法律、法规和规章等规定要求。一是构建医疗器械网络销售质量管理体系。指导网络销售经营者建立健全与网络销售医疗器械相适应的质量管理体系，包括细化质量管理机构职责、丰富人员培训内容、完善体系文件制定、明确体系自查要求等。二是加强医疗器械网络销售质量管理指引。指导网络销售经营者规范网络销售质量管理，包括依法展示企业资质信息和产品信息、完善网络销售记录及相关凭据信息、采取有效措施确保产品运输过程中质量安全等。三是促进网络销售经营者强化风险管理。要求医疗器械网络销售经营者发现产品存在质量问题或者安全隐患时，依法采取暂停产品信息展示、暂停销售等风险控制措施。

五、《规范》对于经营主体信息公示的要求?

《中华人民共和国电子商务法》第十五条明确提出了电子商务经营者应当在其首页显著位置，持续公示营业执照信息、与其经营业务有关的行政许可信息的要求。《规范》贯彻落实医疗器械注册人备案人制度，针对已取得医疗器械经营许可或者办理备案的经营企业、已取得生产许可的注册人以及委托其他企业生产的注册人开展网络销售等三种情形，分别提出了企业主体信息的公示要求，即已取得经营许可或者办理备案的医疗器械经营企业公示医疗器械经营许可证或者第二类医疗器械经营备案凭证；已取得生产许可的医疗器械注册人公示医疗器械生产许可证；委托生产医疗器械的医疗器械注册人展示医疗器械注册证。相关证书凭证可以用图片或者相关电子证书的链接标识等方式进行公示，证书凭证编号应当以文本形式展示。

六、销售角膜接触镜、助听器等有特殊验配要求医疗器械有何特殊要求?

角膜接触镜、助听器等医疗器械在使用前应当经过验配、调试或者试戴。验配过程能够确保产品适合用户的特定需求，降低使用中的不适和潜在风险。

《中华人民共和国电子商务法》第十七条规定电子商务经营者应当全面、真实、准确、及时地披露商品或者服务信息，保障消费者的

comprehensively, truthfully, accurately, and promptly disclose product or service information to safeguard consumers' right to know and right to choose.

In view of the characteristics of these products, the *Specifications* require that for online sales of medical devices such as contact lenses and hearing aids that require specific fitting, online sales operators should prominently and continuously display the following warning messages on the product page, such as "Professional fitting by an eyecare professional is required prior to using this product" and "Prior to hearing aid fitting, professional examination and hearing tests are required. The product should be used under the adjustment, trial fitting, and guidance of a licensed hearing aid fitting professional."

VII. In what aspects do the *Specifications* further strengthen the responsibilities of e-commerce platform operators?

The *Measures on Supervision and Administration of Online Sales of Medical Devices* establish fundamental requirements for e-commerce platform operators in terms of office space, technical conditions, the establishment of management institutions and personnel, as well as the formulation and implementation of quality management systems. Building upon these requirements, the *Specifications* further refine and strengthen the management responsibilities of e-commerce platform operators. Firstly, it clarifies the quality and safety management responsibilities of e-commerce platform operators. E-commerce platform operators should conduct real-name registration of all onboarded online sales operators and review their relevant medical device licenses, filings, as well as the registration and filing status of medical devices sold online. The operators should take effective measures to supervise and manage the business activities of medical device operators on the platform. Secondly, it guides e-commerce platform operators in establishing and improving their quality management systems. It clarifies the responsibilities of the quality management institutions and personnel of e-commerce platform operators, refines the functions of the online trading system, improves the system documents covering the entire process of medical device online trading services, and guides e-commerce platform operators in conducting quality management system audits, corrections, and prevention to ensure the effective operation and continuous improvement of the quality management system. Thirdly, it guides e-commerce platform operators in safeguarding the legitimate rights and interests of consumers in accordance with the law. It clarifies that e-commerce platform operators should establish a complaint and reporting management system, publicly disclose information such as complaint and reporting channels, urge online sales operators on the platform to investigate the causes of reported medical device quality and safety issues, take effective measures to handle and provide feedback, and maintain relevant records promptly. When necessary, the e-commerce platform operators should proactively investigate and handle complaints related to medical device quality and safety issues.

VIII. What are the special requirements of the *Specifications* for e-commerce platform operators in terms of personnel allocation and organizational structure?

In terms of personnel allocation, the *Specifications* adhere to the principle of "people-oriented" and focus on key personnel, clarifying that the legal representative or principal responsible person of e-commerce platform operators should be fully responsible for the quality and safety of medical devices sold online. It specifies that the person responsible for quality and safety management should be responsible for the quality and safety management of online sales of medical devices, assume corresponding quality and safety management responsibilities, and have the adjudicative right to make decisions on medical device quality and safety management within the enterprise. It requires that the legal representatives, principal responsible persons, and quality and safety management personnel of e-commerce platform operators should be familiar with the requirements of laws, regulations, rules, and specifications, and should not be engaged in prohibited activities as stipulated in relevant laws and regulations. In terms of organizational structure, the *Specifications* require that e-commerce platform operators should establish a medical device quality and safety management institution that is commensurate with the scale of medical device online trading services and the level of risk associated with the medical

知情权和选择权。

针对相关产品特点，《规范》要求网络销售角膜接触镜、助听器等有特殊验配要求医疗器械的，网络销售经营者应当在产品页面显著位置持续展示“配戴本产品，应由眼视光专业人士进行验配”“验配助听器前应经过专业的检查及听力测试，并在助听器验配师调试并试听试戴和验配师指导下使用”等警示信息。

七、《规范》从哪些方面进一步压实电商平台经营者责任？

《医疗器械网络销售监督管理办法》在电商平台经营者办公场所和技术条件要求、管理机构和人员设置、质量管理制度制定与执行等方面提出了基本要求。《规范》在此基础上，进一步细化压实电商平台经营者管理责任。一是明确电商平台经营者质量安全管理责任。对入网的网络销售经营者进行实名登记，电商平台经营者要审查其医疗器械相关许可、备案等情况和网络销售医疗器械产品注册、备案情况，采取有效措施对平台内医疗器械经营者的经营行为进行管理。二是指导电商平台经营者建立健全质量管理体系。明确电商平台经营者质量管理机构与人员的职责、细化了网络交易系统功能、健全了覆盖医疗器械网络交易服务全过程的体系文件，指导电商平台经营者开展质量管理体系审核、纠正和预防，保证质量管理体系有效运行并持续改进。三是指导电商平台经营者依法保障消费者合法权益。明确电商平台经营者建立投诉举报管理制度，公开投诉举报方式等信息，督促平台内网络销售经营者对被投诉的医疗器械质量安全问题查明原因，采取有效措施及时处理和反馈，并保存有关记录。必要时，电商平台经营者可以主动对相关的医疗器械质量安全问题投诉进行调查处置。

八、《规范》对于电商平台经营者在人员配置、机构设置方面有哪些特别要求？

在人员配置方面，《规范》坚持“以人为本”的原则，聚焦关键少数，明确电商平台经营者法定代表人或者主要负责人全面负责医疗器械网络销售质量安全。明确质量安全管理负责人负责医疗器械网络销售质量安全管理工作，承担相应的质量安全管理责任，并在企业内部对医疗器械质量安全管理具有裁决权。要求电商平台经营者法定代表人、主要负责人、质量安全管理人员应当熟悉法律、法规、规章、规范等规定要求，不得有相关法律、法规禁止从业的情形。

在机构设置方面，《规范》要求电商平台经营者应当设立与医疗器械网络交易服务规模和医疗器械风险程度相适应的医疗器械质量安全管理机构，并明确机构职责。对于未设立质量安全管理机构的，应指定专门的医疗器械质量安全管理人员履行质量安全管理机构的职责。

devices involved, and clarify the responsibilities of the institution. For those who have not established a quality and safety management institution, they should designate dedicated medical device quality and safety management personnel to fulfill the responsibilities of the quality and safety management institution.

IX. How should e-commerce platform operators handle violations committed by online sales operators on their platforms?

The *Specifications* require that e-commerce platform operators should establish a system for detecting and handling violations of laws and regulations in the online sales of medical devices on their platforms. If they discover that an online sales operator on the platform has failed to display the qualification information of the business entity or product information as required, they should demand that the online sales operator immediately make corrections and record the violation and the rectification. If the sales operator fails to make corrections as required, the platform operator should immediately report to the drug regulatory department at the level of the municipality where the online sales operator is located.

In cases where the platform operator suspects that an online sales operator may be engaging in serious violations—such as selling medical devices without obtaining the necessary licenses or filings, selling unregistered or unfiled medical devices, operating beyond the approved scope of licenses or filings, or selling medical devices that have been publicly prohibited from sale or use by the drug regulatory department, the platform operator should immediately cease providing relevant online trading services, remove associated product information from display, and report to the drug regulatory department at the level of the municipality where the online sales operator is located.

X. How should e-commerce platform operators continuously strengthen the risk management of medical device quality and safety?

The *Specifications* guide e-commerce platform operators to continuously strengthen the risk management of medical device quality and safety by enhancing internal risk monitoring and collecting and analyzing external risk information. The document also outlines a pathway and key indicators for enterprises to follow in strengthening such risk management. Firstly, regarding the implementation of responsibilities for personnel in key positions, the *Specifications* clarify that the legal representative or principal responsible person of the e-commerce platform should conduct at least one quarterly work consultation and summary on the quality and safety risks of medical device online sales on the platform, thereby reinforcing the responsibilities of key personnel. Secondly, the *Specifications* guide e-commerce platform operators to strengthen internal monitoring of medical device quality and safety risks through methods such as analyzing purchaser complaints and conducting quality inspections. At the same time, the *Specifications* require that e-commerce platform operators should actively pay attention to and collect regulatory dynamic information such as medical device supervision and inspection, administrative penalties, supervisory sampling inspections, and product recalls published on the website of the drug regulatory department, and promptly conduct self-inspections. Enterprises are required to take timely risk control measures in response to product quality and safety risks identified through monitoring and self-inspection, including internal rectification, suspension of product information release, suspension of sales, cessation of online trading services, and reporting to regulatory authorities, in order to comprehensively strengthen the management of medical device quality and safety risks.

(May 09, 2025)

九、电商平台发现入网的网络销售经营者存在违法违规行为时如何处置？

《规范》要求，电商平台经营者应当建立平台内医疗器械网络销售违法违规行为发现处置制度，发现平台内网络销售经营者存在未按要求展示经营主体资质信息、未按要求展示产品信息等行为，应当要求网络销售经营者立即改正，并记录其违规行为和整改情况。未按要求改正的，应当立即向网络销售经营者所在地设区的市级药品监督管理部门报告。

电商平台经营者发现平台内网络销售经营者可能存在未经许可或者备案销售医疗器械，销售未经注册或者未备案医疗器械，超出许可或者备案的经营范围、经营方式销售医疗器械，销售药品监督管理部门公布的不得销售、使用的医疗器械等严重违法行为的，应当立即停止提供相应网络交易服务，停止展示医疗器械相关信息，并向网络销售经营者所在地设区的市级药品监督管理部门报告。

十、电商平台经营者应如何持续加强医疗器械质量安全风险管理？

《规范》指导电商平台经营者通过加强内部风险监测和收集分析外部风险信息等方式，持续加强医疗器械质量安全风险管理，并为企业规划了持续加强医疗器械质量安全风险管理的路径和关键指标。

首先是关键岗位人员的责任落实，《规范》明确了电商平台法定代表人或者主要负责人对平台医疗器械网络销售质量安全风险情况每季度至少进行一次工作会商总结，以压实关键人员责任。其次，《规范》指导电商平台经营者可以通过开展购货者投诉分析、质量检验等方式加强医疗器械质量安全风险内部监测。同时，《规范》要求电商平台经营者应当主动关注和收集药品监督管理部门网站发布的医疗器械监督检查、行政处罚、监督抽检、产品召回等监管动态信息，并及时开展自查。要求企业对监测和自查中发现的产品质量安全风险，及时采取自查整改、暂停发布产品信息、暂停销售、停止提供网络交易服务并上报监管部门等风险控制措施，全面强化医疗器械质量安全风险管理。

(May 09, 2025)

Cosmetics

Announcement of the National Medical Products Administration (NMPA) on Matters Related to the Administration of the *Inventory of Existing Cosmetic Ingredients (IECIC)* (No. 61 of 2025)

化妆品

国家药监局关于《已使用化妆品原料目录》管理有关事项的公告（2025年第61号）

To implement the *Regulations on Supervision and Administration of Cosmetics,* further regulate the administration of cosmetic ingredients, and encourage innovation in raw materials, the following matters concerning the *Inventory of Existing Cosmetic Ingredients* (hereinafter referred to as the *Inventory*) are hereby announced:

I. In accordance with the *Regulations on Supervision and Administration of Cosmetics,* cosmetic ingredients that have been registered or filed, and have completed a three-year safety monitoring period without any safety concerns, should be included in the *Inventory*. To facilitate ingredient management, the NMPA has divided the *Inventory* into two sublists: List I and List II. The *Inventory* issued by the NMPA in 2021 has been partially revised and refined, and will now be managed as List I of the *Inventory,* while new cosmetic ingredients that have completed the safety monitoring period will be included in the *Inventory* and managed as List II of the *Inventory*.

II. List I of the *Inventory* is based on the *IECIC* issued in 2021, with the following adjustments: the “Maximum Historical Usage Level” item has been removed; the Chinese, INCI, and English names of relevant ingredients have been standardized; and ingredient remarks have been revised in accordance with the Technical Specification for the Safety of Cosmetics. List II of the *Inventory* includes two new cosmetic ingredients—N-Acetylneuraminic Acid and β-Alanyl Hydroxyprolyl Diaminobutyric Acid Benzylamide—which have been filed, have completed the three-year safety monitoring period, and have been assessed as compliant with applicable regulatory requirements.

III. The NMPA has established a dynamic adjustment mechanism for the *Inventory*. The *Inventory* will be continuously updated and improved based on scientific research progress, industry development, and regulatory practices. Adjustments may include additions, refinements, and corrections.

IV. Effective immediately, the NMPA will no longer issue the *Inventory* in the form of official announcements. All future updates to the *Inventory* and related adjustment notes will be proactively disclosed on the official NMPA website. The query channel is the "Cosmetics → Cosmetic Query → Inventory of Existing Cosmetic Ingredients" on the official website of NMPA.

It is hereby announced.

National Medical Products Administration
June 23, 2025
(June 24, 2025)

为贯彻执行《化妆品监督管理条例》，进一步规范化妆品原料管理，鼓励原料创新，现就《已使用化妆品原料目录》（以下简称《目录》）管理有关事项公告如下：

一、根据《化妆品监督管理条例》规定，经注册、备案的化妆品新原料投入使用后3年安全监测期满未发生安全问题的，纳入《目录》。为便于已使用化妆品原料管理，国家药监局将《目录》分为I和II两个清单管理。对国家药监局2021年发布的《目录》进行局部修改完善，作为《目录》I管理。化妆品新原料安全监测期满纳入《目录》的，作为《目录》II管理。

二、《目录》I在国家药监局2021年发布的《目录》基础上，不再保留“产品最高历史使用量”这一项目，对有关原料中文名称或者INCI名称/英文名称予以规范，同时根据《化妆品安全技术规范》调整有关原料的备注内容等。《目录》II纳入“N-乙酰神经氨酸”和“β-丙氨酰羟脯氨酰二氨基丁酸苄胺”两个化妆品新原料，上述两个新原料经备案后，安全监测期已满3年，经评估符合相关法规要求。

三、国家药监局建立《目录》动态调整机制，对《目录》实行动态更新，根据科学研究进展、行业发展和监管工作实际等，对《目录》进行补充、完善、勘误等。

四、自即日起，国家药监局不再以公告形式发布《目录》，更新后的《目录》以及《目录》调整说明将通过国家药监局网站及时主动公开。查询渠道为国家药监局官方网站“化妆品—化妆品查询—已使用化妆品原料目录”。

特此公告。

国家药监局
2025年6月23日
（2025-06-24）

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
- The translation is credited for the support of RDPAC and ISPE.

备 注：
- Newsletter中所有中文信息均摘自报刊及网络。英文均系中文翻译。如有出入，请以中文为准。
- 电子版Newsletter阅览请登录网站http://www.ccfdie.org
- 本刊翻译感谢中国外商投资企业协会药品研制和开发工作委员会（RDPAC）和国际制药工程协会（ISPE）支持。

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