2026 Volume 4

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国药品国际交流中心

Announcement of the National Medical Products Administration, the National Health Commission, the National Administration of Traditional Chinese Medicine, and the National Disease Control and Prevention Administration on Issuing the *Good Clinical Practice* (No. 50, 2026)

To optimize the quality management of drug clinical trials, further foster a standardized and efficient clinical research ecosystem, and support innovation in biopharmaceutical R&D, the National Medical Products Administration (NMPA), together with the National Health Commission (NHC), the National Administration of Traditional Chinese Medicine (NATCM), and the National Disease Control and Prevention Administration (NDCPA), has revised the *Good Clinical Practice*, which is hereby issued and shall come into force on September 1, 2026. The Announcement of the NMPA and the NHC on Issuing the *Good Clinical Practice* (Announcement No. 57 of 2020) is hereby repealed simultaneously.

It is hereby announced.

Annexes: 1. Good Clinical Practice (2026 Revision)

2. Q&A Document on *Good Clinical Practice* (2026 Revision)

National Medical Products Administration
National Health Commission
National Administration of Traditional Chinese Medicine
National Disease Control and Prevention Administration
May 21, 2026
(2026-06-08)

国家药监局 国家卫生健康委 国家中医药局 国家疾控局关于发布药物临床试验质量管理规范的公告（2026年第50号）

为优化药物临床试验质量管理，进一步培育规范高效的临床研发生态，支持生物医药研发创新，国家药品监督管理局会同国家卫生健康委员会、国家中医药管理局和国家疾病预防控制局修订了《药物临床试验质量管理规范》，现予发布，自2026年9月1日起施行。国家药监局 国家卫生健康委《关于发布药物临床试验质量管理规范的公告》（2020年第57号）同时废止。

特此公告。

附件：1.药物临床试验质量管理规范（2026年修订）

2.《药物临床试验质量管理规范（2026年修订）》问答文件

国家药监局
国家中医药局
国家卫生健康委
国家疾控局
2026年5月21日
（2026-06-08）

Good Clinical Practice for Drugs (2026 Revision): Questions and Answers

I. What is the background for revising the Good Clinical Practice (GCP)?

Drug clinical trials constitute a critical stage in drug research and development (R&D). The CPC Central Committee and the State Council attach great importance to the development of the biopharmaceutical industry. With the support of national policies and joint efforts of the industry, during the "14th Five-Year Plan" period, China's clinical R&D system has rapidly developed, becoming deeply integrated into the global R&D industry chain. The number of innovative drug clinical trials has increased significantly, and China's share in global clinical R&D has steadily risen.

In recent years, as the globalization of the biopharmaceutical industry accelerates, both industry and regulatory authorities have continuously updated clinical R&D technologies and concepts, focusing on improving the quality and efficiency of drug clinical trials. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) carried

《药物临床试验质量管理规范（2026年修订）》问答文件

一、修订《药物临床试验质量管理规范》的背景？

药物临床试验是药物研发的关键环节。党中央、国务院高度重视生物医药产业发展，在国家政策支持和行业共同努力推动下，“十四五”期间，我国临床研发体系加速发展，深度嵌入全球研发产业链，创新药临床试验数量显著增加，在全球临床研发中的占比稳步提升。

近年来，随着全球生物医药产业全球化步伐加快，业界和监管机构持续更新临床研发技术和理念，着力提升药物临床试验质量和效率。国际人用药品注册技术协调会（ICH）开展药物临床试验质量管理规范技术协调，于2025年1月发布《E6（R3）：药物临床试验质量管理规范技

Published by
China Center for Medical Products International Exchange

out technical harmonization of Good Clinical Practice and released the E6(R3) Guideline for Good Clinical Practice (i.e., ICH GCP) in January 2025, aiming to better guide flexible trial designs and emphasizing the core concepts of quality by design, fitness for purpose, and proportionality to risk. The NMPA has been deeply involved in the harmonization of this guideline in the early stage, and has fully implemented it for drug clinical trials conducted after March 31, 2026.

China's GCP serves as a key normative document guiding scientific and compliant drug R&D and regulatory enforcement in line with international standards. Since the implementation of the 2020 version of GCP, it has played an important role in the standardized development of drug clinical trials in China, effectively guiding the conduct and regulatory practices of clinical trials. To further optimize the quality management of drug clinical trials in China, it is necessary to review and summarize prior experiences in clinical trial implementation, further incorporate global advancements in clinical trial technologies and evolving concepts, and revise the 2020 version of GCP accordingly.

II. How does GCP align with laws, regulations, other normative documents, and technical guidelines?

The Good Clinical Practice is a normative document that guides regulatory authorities, sponsors, drug clinical trial institutions, and other entrusted entities in conducting drug clinical trials, and serves as the basis for regulatory enforcement.

At the level of laws and regulations, GCP aligns with the requirements of higher-level laws such as the Drug Administration Law, Vaccine Administration Law, Regulations for the Implementation of the Drug Administration Law, and Provisions for Drug Registration.

At the level of normative documents, GCP aligns with normative documents such as the *Provisions for the Administration of Drug Clinical Trial Institutions, Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial)*, and the *Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings* (Guowei Kejiaofa [2023] No. 4) jointly issued by four departments, including the National Health Commission. Content already specified in dedicated normative documents is not repeated, and the GCP may provide cross-references as needed.

At the level of guidelines, emphasis is placed on alignment with ICH E6(R3), refining and improving regulatory rules to maintain consistency in fundamental principles and requirements. Where E6(R3) calls for compliance with local regulatory requirements, GCP further clarifies these requirements. Operational details, recommended practices, and conceptual descriptions in E6(R3) are not incorporated into China's GCP but are implemented in full through E6(R3), allowing flexibility in clinical trial implementation. Key points for verification and inspection, as well as other relevant technical guidelines in China, are well aligned with GCP and E6(R3) to strengthen implementation guidance.

III. What are the adjustments and considerations for each chapter in the draft revision of GCP?

The draft revision of GCP is divided into six chapters: General Provisions, Ethics Review Committee, Principal Investigator and Drug Clinical Trial Institution, Sponsor, Data Governance, and Supplementary Provisions, encompassing fifty-four articles. Compared to the 2020 version of GCP, a new chapter on data governance has been added. Given that E6(R3) provides detailed explanations on the trial protocol, Investigator's Brochure, essential document management, terminology, and definitions, to reduce unnecessary duplication and further strengthen alignment with ICH E6(R3), the revised GCP deletes the original chapters on the trial protocol, investigator's brochure, and essential document management, and simplifies the terminology section to retain only trial participants and terms suited to China's clinical trial practices. For specific implementation of the relevant content, please

术指导原则》（即ICH GCP），旨在更好指导灵活的试验设计，强调质量源于设计、符合目的和风险相称的核心理念。我局前期深入参与该指导原则协调，于2026年3月31日后全面实施。

我国《药物临床试验质量管理规范》（GCP）是指导药物研发科学合规、监管执法符合国际标准的重要规范性文件。现行的2020版GCP实施以来对我国药物临床试验规范化发展发挥了重要作用，有效指导了我国临床试验实施和监管实践。为进一步优化我国药物临床试验质量管理，有必要梳理总结我国临床试验前期实施经验，进一步吸纳全球临床试验技术发展和理念更新，对2020版GCP进行修订。

二、GCP如何与法律法规、其他规范性文件和技术指导原则衔接？

《药物临床试验质量管理规范》是规范性文件，指导监管部门、申办者、药物临床试验机构及其他接受委托的机构开展药物临床试验工作，是监管执法依据。

在法律法规层面，与《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》等上位法有关要求对接。

在规范性文件层面，与《药物临床试验机构管理规定》《药物临床试验机构监督检查办法（试行）》、国家卫生健康委等四部门发布的《涉及人的生命科学和医学研究伦理审查办法》（国卫科教发〔2023〕4号）等规范性文件衔接，已有专门规范性文件规定的内容不再重复，GCP中可留接口。

在指导原则层面，重点做好与ICH E6（R3）衔接，提炼完善监管规则，保持基本原则和要求一致；E6（R3）中遵循当地监管要求的，进一步明确监管要求；E6（R3）中属于操作细则、建议性做法和理念性描述的，不纳入我国GCP，而是采取全文实施E6（R3）方式，为临床试验实施灵活性预留空间；核查、检查要点和我国其他相关技术指导原则与GCP和E6（R3）做好衔接，加强实施指导。

三、GCP修订稿各章节的调整情况及考虑是什么？

GCP修订稿分为总则、伦理审查委员会、主要研究者和药物临床试验机构、申办者、数据治理、附则六个章节，五十四个条款。与2020版GCP相比，增加了数据治理章节。鉴于E6（R3）对试验方案、研究者手册、必备文件管理、术语及其定义已有详细阐述，为减少不必要重复，进一步加强与ICH E6（R3）衔接，GCP修订中删除了原有的试验方案、研究者手册与必备文件管理三个章节，简化术语部分，仅保留试验参与者和适应我国临床试验实践的

refer to the Chinese version of E6(R3). Requirements in the 2020 GCP regarding the drafting of investigator's brochures for traditional Chinese medicine and ethnic medicines will subsequently be incorporated into technical guidelines for issuance.

IV. What conceptual adjustments have been made in the draft revision of GCP?

China's GCP revision fully incorporates the core concepts from ICH E6(R3) of quality by design, fitness for purpose, and proportionality to risk, which are included in the General Provisions. Principle-based requirements for applying these core concepts across all stages of drug clinical trials are also specified. At the same time, to support the application of new technologies and methods in clinical trials, the General Provisions delineate boundaries for their use, stating that new technologies and methods applied in clinical trials must comply with current ethical, scientific, and relevant legal and regulatory requirements.

V. What measures does the draft revision of GCP take to further strengthen accountability, protect trial participants, and optimize management requirements?

Regarding accountability, considering that drug clinical trials in China are invariably conducted by teams and referencing the definition of principal investigator in E6(R3), the draft revision clarifies that the principal investigator is the ultimate responsible person at the clinical trial site and specifies matters that, in principle, cannot be delegated by the principal investigator. Meanwhile, it is clarified that the sponsor is the ultimate responsible party for activities related to the clinical trial, and both the principal investigator and sponsor bear final responsibility for their delegated activities.

In terms of protecting trial participants, the General Provisions further clarify the critical role of ethical review and informed consent in safeguarding the rights, interests, and safety of trial participants; strengthen the Ethics Review Committee's review of special populations, informed consent, and issues of serious and persistent non-compliance; the Sponsor chapter specifies that the sponsor shall update the trial protocol, Investigator's brochure, and informed consent materials as necessary based on safety information assessments during the trial. The informed consent form shall be adequate, complete, understandable, and comply with ethical review and related requirements; it also specifies requirements for the principal investigator to report serious adverse events to the Ethics Review Committee.

In optimizing management, the revision responds to the specific needs of all parties involved in clinical trials by further streamlining processes and clarifying responsibilities. For example: In the Ethics Review Committee chapter, it is required that the Ethics Review Committee conduct reviews in accordance with relevant regulations of the competent health administration department(s), and requirements for key review content and review methods are refined; the reporting process for safety information is optimized, and responsibilities are clarified; the Sponsor chapter improves requirements for maintaining blinding at all stages of the trial, adds requirements for the sponsor to manage risks during clinical trial implementation, and specifies requirements for and status of electronic signatures, among others.

VI. How does the draft revision of GCP strengthen quality management requirements?

The quality of design and implementation in drug clinical trials directly affects the rights, interests and safety of trial participants, as well as the reliability of clinical trial results. This revision explicitly states that quality management shall run through the entire process of drug clinical trials, and introduces the terms "quality management of drug clinical trials" and "quality management system for drug clinical trials" to unify understanding among all parties, clarify the objectives, pathways, and methods of quality management, and guide sponsors and drug clinical trial institutions to conduct quality management scientifically and efficiently.

(2026-06-08)

术语，相关内容具体执行参照E6（R3）中文版。2020版GCP中关于中药民族药研究者手册撰写的有关要求，后续纳入技术指导原则发布。

四、GCP修订稿在理念方面有哪些调整？

我国GCP修订充分吸收了ICH E6（R3）质量源于设计、符合目的和风险相称的核心理念，纳入总则部分，并对上述核心理念在药物临床试验各环节的应用提出原则性要求。同时，为支持新技术、新方法在临床试验中的应用，总则部分为新技术、新方法应用划定边界，提出新技术、新方法在临床试验应用应符合当前伦理、科学和相关法律法规要求的原则。

五、GCP修订稿对进一步强化主体责任、保护试验参与者、优化管理要求等方面有何举措？

在主体责任方面，考虑到我国药物临床试验均由团队实施的实际情况，结合E6（R3）的主要研究者定义，修订稿明确主要研究者是临床试验现场的最终责任人，并明确了主要研究者原则上不得授权的事项。同时，明确申办者是临床试验相关活动的最终责任人，主要研究者和申办者对其授权委托活动承担最终责任。

在保护试验参与者方面，总则部分进一步明确伦理审查和知情同意对保障试验参与者权益和安全的重要作用；加强伦理审查委员会对涉及特殊群体、知情同意和严重持续不依从问题的审查；申办者章节明确申办者应根据试验期间安全性信息评估结果，对试验方案、研究者手册和知情同意材料进行必要的更新，知情同意书应当充分、完整、易懂，符合伦理审查等有关要求；明确主要研究者向伦理审查委员会报告严重不良事件有关要求。

在优化管理方面，回应临床试验各参与方的具体诉求，进一步优化流程，明确职责。比如：在伦理审查委员会章节要求伦理审查委员会开展伦理审查工作应当符合卫生健康主管部门有关规定，完善伦理审查委员会应当重点审查的内容及审查方式要求；优化安全性信息的报告流程，明确相关责任方；申办者章节完善保持试验各阶段盲态要求，增加申办者对临床试验实施风险管理的要求；明确电子签名的要求及地位等。

六、GCP修订稿如何强化质量管理要求？

药物临床试验的设计和实施质量直接关系试验参与者的权益和安全，以及临床试验结果的可靠性。本次修订明确质量管理应当贯穿药物临床试验全过程，并增加药物临床试验质量管理和药物临床试验质量管理体系术语，以统一各方认识，明确药物临床试验质量管理的目标、路径和方法，指导申办者和药物临床试验机构科学高效开展质量管理工作。

(2026-05-15)

Work Procedure for the Protection of Drug Regulatory Data

Article 1 In order to standardize the drug regulatory data protection (hereinafter referred to as data protection), this Working Procedure is hereby formulated in accordance with *the Drug Administration Law of the People's Republic of China, the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, the Provisions for Drug Registration, and the Implementation Measures for Drug Regulatory Data Protection* (hereinafter referred to as the Implementation Measures).

Article 2 The Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as CDE), under the guidance of the National Medical Products Administration (hereinafter referred to as NMPA), shall be responsible for the specific implementation of data protection.

When accepting a marketing registration application for chemical drugs and biological products, the data protection application submitted by the drug registration applicant (hereinafter referred to as the applicant) shall be reviewed concurrently. The review shall determine whether data protection should be granted.

During the data protection period, when accepting a marketing registration application or supplementary application that relies on the protected data of another marketing authorization holder (hereinafter referred to as the holder), the relevant information of the protected data being relied upon shall be concurrently reviewed. If, upon completion of the technical review, the protected data being relied upon are still within the protection period and the holder has not consented to such reliance, the review shall be suspended.

Article 3 The applicant applying for data protection shall submit the data protection application together with the marketing registration application, truthfully complete the relevant information in the application form, and specify the data protection period. The applicant shall be responsible for the authenticity of the data protection information submitted.

Article 4 Upon acceptance of a drug marketing registration application, the CDE shall concurrently conduct a formal review of the data protection application submitted by the applicant and mark the variety after acceptance.

Article 5 The CDE shall review applications for drug regulatory data protection during the review process in accordance with the relevant requirements of the Implementation Measures. For those meeting the requirements, a recommendation on the protection period to be granted shall be put forth, and the data protection period shall be specified. For those failing to meet the requirements, a recommendation not to grant data protection shall be made.

Article 6 For the varieties that are provided with data protection when approved for marketing, the CDE shall disclose the data protection-related contents approved in the registration approval documents in the special column of varieties under drug regulatory data protection.

Article 7 After a drug has obtained data protection, other applicants may submit marketing registration applications or supplementary applications for drugs relying on the protected data within one year prior to the expiration of the data protection period. When the applicants obtain the study data by themselves or rely on the protected data with the consent of the holders, they may directly submit the drug marketing registration applications or supplementary applications. Where the applicants rely on the protected data with the consent of the holders, they shall provide *the Agreement on Consent to Drug Regulatory Data Reliance* signed by both parties.

When submitting the drug marketing registration applications or supplementary applications, the applicants shall specify related information on whether they are relying on protected data in the application forms and specify each of them separately for those relying on the protected data of multiple varieties.

药品试验数据保护工作程序

第一条 为规范药品试验数据保护（以下简称数据保护）的具体实施工作，根据《中华人民共和国药品管理法》《中华人民共和国药品管理法实施条例》《药品注册管理办法》和《药品试验数据保护实施办法》(以下简称《实施办法》)，制定本工作程序。

第二条 国家药品监督管理局药品审评中心（以下简称药审中心）在国家药品监督管理局（以下简称国家药监局）的指导下，负责数据保护的具体实施工作。

在受理化学药品和生物制品上市注册申请时，同步审查药品注册申请人（以下简称申请人）提交的数据保护申请。审评过程中判断是否给予数据保护。

数据保护期内，在受理依赖其他药品上市许可持有人（以下简称持有人）受保护数据的上市注册申请或者补充申请时， 同步审查被依赖受保护数据的相关信息。完成技术审评后，如被依赖的受保护数据仍在保护期内且申请人未获得持有人同意的，中止审评。

第三条 申请数据保护的， 申请人应当在提交上市注册申请的同时提出数据保护申请，在申请表中如实填写相关信息，明确数据保护的期限。申请人需对其提交的数据保护相关信息的真实性负责。

第四条 药审中心在受理药品上市注册申请时，同步形式审查申请人提交的数据保护申请，受理后对该品种进行标记。

第五条 药审中心按照《实施办法》的相关要求，在审评过程中对药品试验数据申请进行审查。符合要求的，提出给予保护期限的建议，并明确数据保护期限。不符合要求的，提出不给予数据保护的建议。

第六条 对于批准上市时给予数据保护的品种，药审中心在药品试验数据保护品种专栏公开注册批准文件中批准的数据保护相关内容。

第七条 药品获得数据保护后，其他申请人在数据保护期届满前 1 年内可以提交依赖该受保护数据的药品上市注册申请或者补充申请。对于申请人自行取得试验数据或者经持有人同意依赖受保护数据的，可直接提交药品上市注册申请或者补充申请。对于经持有人同意依赖受保护数据的， 申请人需提供双方签署的《药品试验数据同意依赖协议》。

提交药品上市注册申请或者补充申请时，申请人需在申请表中明确是否依赖受保护数据

Article 8 When accepting drug marketing registration applications or supplementary applications, the CDE shall simultaneously conduct a formal review of related information submitted by applicants on whether they rely on protected data and mark the applications after acceptance.

Article 9 When CDE completes the technical review, if the protected data relied upon are still within the data protection period and the applicants fail to obtain the consent of the holders of protected data, the data protection period shall be indicated, the review shall be suspended, and the reasons for suspension shall be "drug regulatory data protection".

Article 10 Beginning on the 14th working day prior to the expiration of the data protection period, varieties for which review was previously suspended on account of the data protection shall be resumed.

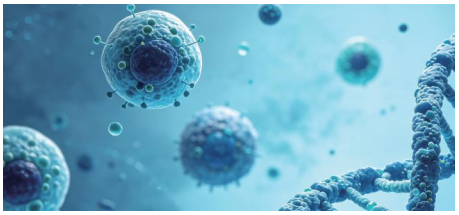
Article 11 Where data protection is terminated, the CDE shall update related information in the special column of varieties under drug regulatory data protection. From the date on which the NMPA issues the announcement on termination of data protection, the CDE may accept drug marketing registration applications and supplementary applications submitted by other applicants in reliance on the protected data. The review of the varieties previously suspended due to involvement in the protected data shall be resumed.

Article 12 The applicants may communicate with the CDE on issues related to data protection before submitting the drug marketing registration applications or supplementary applications or during the review in accordance with the requirements of *the Measures for the Administration of Drug Research and Development and Technical Review Communication of the Center for Drug Evaluation of the National Medical Products Administration.*

Article 13 For new issues and controversial issues encountered during the implementation of data protection, the CDE shall promptly organize study, and communicate with applicants when necessary. For issues that cannot be resolved by CDE shall be promptly submitted to the NMPA for study.

Article 14 The Working Procedure shall take effect as of the date of public release.

(2026-05-15)



第八条 在受理药品上市注册申请或者补充申请时，药审中心同步形式审查申请人提交的是否依赖受保护数据的相关信息，受理后进行标记。

第九条 药审中心完成技术审评时，如果被依赖的受保护数据仍在数据保护期内， 且申请人未获得受保护数据持有人同意的，注明数据保护期限，中止审评，中止理由为" 药品试验数据保护"。

第十条 自数据保护期限届满前第 14 个工作日，对此前因涉及该数据保护中止审评的品种恢复审评。

第十一条 数据保护被终止的，药审中心在药品试验数据保护品种专栏更新相关信息。自国家药监局发布终止数据保护公告之日起，药审中心可以受理其他申请人提出的依赖该受保护数据提交的药品上市注册申请和补充申请。对于此前涉及该受保护数据中止审评的品种恢复审评。

第十二条 申请人可以在药品上市注册申请或者补充申请申报前或者审评过程中就数据保护相关问题，按照《国家药品监督管理局药品审评中心药物研发与技术审评沟通交流管理办法》的要求， 与药审中心沟通交流。

第十三条 数据保护工作实施过程中遇到的新问题以及争议问题，药审中心及时组织研究，必要时与申请人进行沟通交流。对于药审中心无法解决的问题，及时提交至国家药监局研究。

第十四条 本工作程序自公开发布之日起执行。

(2026-05-15)

Announcement of the National Medical Products Administration on Issuing the Provisions on the Administration of Registration, Filing and Dossier of New Cosmetic Raw Materials

To accelerate the research, development and innovation of new cosmetic raw materials and promote the high-quality development of the industry, the National Medical Products Administration (NMPA) has formulated the *Provisions on the Administration of Registration, Filing and Dossier of New Cosmetic Raw Materials in accordance with* the *Regulations on Supervision and Administration of Cosmetics, the Provisions for Registration and Filing of Cosmetics* and other relevant provisions. The Provisions are hereby issued and shall come into force on July 15, 2026.

The Announcement of the National Medical Products Administration on Issuing the Provisions on the Administration of Registration, Filing and Dossier Management of New Cosmetic Raw Materials (No. 31 of 2021) shall be repealed simultaneously.

It is hereby announced.

National Medical Products Administration

June 25, 2026

(2026-06-26)

国家药监局关于发布化妆品新原料注册备案及资料管理规定的公告（2026年第59号）

为加快化妆品新原料研发创新，促进产业高质量发展，根据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关规定，国家药监局组织制定了《化妆品新原料注册备案及资料管理规定》，现予发布，自2026年7月15日起施行。《国家药监局关于发布〈化妆品新原料注册备案资料管理规定〉的公告》（2021年第31号）同时废止。

特此公告。

国家药监局

2026年6月25日

(2026-06-26)

Provision on the Administration of Registration, Filing and Dossier Management of New Cosmetic Raw Materials

(Issued by Announcement No. 31 of the NMPA on February 26, 2021; revised by Announcement No. 59 of the NMPA on June 25, 2026; effective as of July 15, 2026)

Article 1 This Provision is formulated in accordance with the requirements of the Regulations on Supervision and Administration of Cosmetics and the *Measures for the Administration of Cosmetics Registration and Filing*, for the purpose of standardizing the administration of registration and filing of new cosmetic ingredients.

Article 2 The documents submitted by registrants and filing persons of new cosmetic ingredients when applying for registration or conducting filing of new cosmetic ingredients shall comply with the requirements of this Provision.

Article 3 The registration and filing documents of new cosmetic ingredients shall be based on scientific research and describe the properties, characteristics, and safe use requirements of new cosmetic ingredients in a comprehensive, authentic, accurate, and standardized manner.

Registrants and filing persons of new cosmetic ingredients shall be responsible for the authenticity, accuracy, completeness, legality, and traceability of the submitted documents.

Article 4 Registrants, filing persons of new cosmetic ingredients, or domestic responsible persons shall apply for registration or conduct filing through the cosmetic registration and filing information service platform (hereinafter referred to as the "information service platform") in accordance with relevant provisions. The electronic version of the registration and filing documents filled in and uploaded to the information service platform shall be consistent with the corresponding paper version.

Article 5 Before applying for registration or conducting filing of new cosmetic ingredients, registrants and filing persons of new cosmetic ingredients shall fill in the following information through the information service platform to complete user information registration: (1) Information of registrants and filing persons of new cosmetic ingredients; (2) Overview of the safety risk monitoring and assessment system of registrants and filing persons of new cosmetic ingredients; (3) Where the registrant or filing person of new cosmetic ingredients is an overseas entity, the domestic responsible person shall fill in the information and submit the originals of the letter of authorization for the domestic responsible person and the notarial certificate thereof.

Where a domestic enterprise holds multiple identities, such as registrant, filing person, or domestic responsible person of new cosmetic ingredients at the same time, or is authorized as the domestic responsible person for multiple overseas registrants or filing persons of new cosmetic ingredients, it may obtain corresponding user permissions after submitting all relevant documents at one time. Existing users may supplement relevant documents and adjust user authorities according to actual conditions.

Article 6 The letter of authorization for the domestic responsible person shall at least specify the following contents and information: (1) Names of the registrant, the filing person, and the domestic responsible person of new cosmetic ingredients; (2) Scope of authorization; (3) Term of authorization.

The same new cosmetic ingredient shall not be authorized to more than one domestic responsible person. The domestic responsible person shall carry out the registration or filing of new cosmetic ingredients within the scope of authorization. The domestic responsible person shall submit a letter of authorization for extending the authorization term before the expiration of the authorization term specified in the letter of authorization. Where it fails to submit as required, the corresponding permissions of the domestic responsible person's account shall be frozen upon expiration and shall be restored after such submission.

Article 7 When the following information and documents of registrants, filing persons of new cosmetic ingredients, or domestic responsible persons change, they shall be updated in a timely

化妆品新原料注册备案及资料管理规定

（2021年2月26日国家药监局第31号公告发布，2026年6月25日国家药监局第59号公告修改，自2026年7月15日起实施）

第一条 为规范化妆品新原料注册备案管理工作，根据《化妆品监督管理条例》《化妆品注册备案管理办法》等要求，制定本规定。

第二条 化妆品新原料注册人、备案人申请化妆品新原料注册或者进行备案时提交的资料，应当符合本规定要求。

第三条 化妆品新原料注册、备案资料应当以科学研究为基础，全面、真实、准确、规范地描述新原料的性状、特征和安全使用要求等。

化妆品新原料注册人、备案人对所提交资料的真实性、准确性、完整性、合法性和可追溯性负责。

第四条 化妆品新原料注册人、备案人或者境内责任人应当按照规定，通过化妆品注册备案信息服务平台（以下简称信息服务平台）申请注册或者进行备案，信息服务平台中填写、上传的注册、备案资料电子版应当与相应的纸质版保持一致。

第五条 化妆品新原料注册人、备案人在申请新原料注册或者进行新原料备案前，应当通过信息服务平台填报以下信息，进行用户信息登记：

（一）化妆品新原料注册人、备案人信息；

（二）化妆品新原料注册人、备案人安全风险监测和评价体系概述；

（三）化妆品新原料注册人、备案人为境外的，应当由境内责任人填报信息，同时提交境内责任人授权书及其公证书的原件。

同一境内企业同时具有化妆品新原料注册人、备案人或者境内责任人等多重身份的，或者经授权作为多个境外化妆品新原料注册人、备案人的境内责任人的，可以一次性提交全部相关资料后取得相应的用户权限。已有用户可以根据实际情况补充提供相关资料，调整用户权限。

第六条 境内责任人授权书应当至少载明以下内容和信息：

（一）化妆品新原料注册人、备案人和境内责任人名称；

（二）授权范围；

（三）授权期限。

同一化妆品新原料不得授权多个境内责任人。境内责任人应当按照授权范围开展化妆品新原料注册或者备案工作。境内责任人应当在授权书所载明的授权期限届满前提交延长授权期限的授权书，未按规定提交的，届满时境内责任人账户相应权限予以冻结，直至提交后恢复权限。

第七条 化妆品新原料注册人、备案人或者境内责任人的以下信息资料发生变化时，应当及时进行更新，确保信息服务平台中的相关信

manner to ensure that the relevant information and documents on the information service platform are authentic and accurate: (1) When information such as the legal representative and contact information of the registrant, filing person, or domestic responsible person changes, the user shall update it on the information service platform by itself; (2) When other basic information of the registrant, filing person, or domestic responsible person, the overview of the safety risk monitoring and assessment system for new cosmetic ingredients, or the scope and term of authorization of the domestic responsible person changes, an information update form for registrants and filing persons of new cosmetic ingredients shall be submitted, and relevant documents shall be submitted as required to complete the update of relevant information and documents.

Where the name or address of an overseas registrant or filing person changes, the original relevant certification document issued by the competent government department or relevant institution of the country (region) where it is located, certifying that the entity remains unchanged, shall be provided. If the original cannot be submitted, a copy notarized by a Chinese notary office or confirmed by the Chinese embassy (consulate) shall be provided.

Where the name or address of a domestic responsible person changes, the original relevant certification document issued by the competent government department or relevant institution of China, certifying that the subject remains unchanged, shall be provided.

Where the scope of authorization of the domestic responsible person changes, the new scope of authorization shall cover the original scope of authorization. Where only the authorization term is updated, other contents of the letter of authorization shall not be changed.

Where the domestic responsible person is changed, a letter of authorization meeting the requirements of Article 6 of this Provision, as well as a letter of commitment by the proposed new domestic responsible person to assume all relevant responsibilities of the original domestic responsible person, shall be submitted.

Article 8 To apply for registration or conduct filing of a new cosmetic ingredient, the registrant or filing person shall submit the following documents: (1) Name, address, and contact information of the registrant, filing person, and domestic responsible person; (2) Research and development report of the new ingredient; (3) Research documents on the preparation process, stability, and quality control standards of the new ingredient; (4) Safety assessment documents of the new ingredient.

Registrants and filing persons of new cosmetic ingredients shall formulate and provide the technical specifications for the new cosmetic ingredient based on the relevant technical information in the registration and filing documents. The technical specifications shall include basic information, purpose of use, safe usage amount, precautions, period of use, and other contents.

Article 9 The toxicological and human safety reports of new cosmetic ingredients submitted by registrants and filing persons shall be issued by institutions that have obtained China Inspection Body and Laboratory Mandatory Approval (CMA) for relevant items, obtained accreditation from the China National Accreditation Service for Conformity Assessment (CNAS) for relevant items, or comply with Good Clinical Practice (GCP) or Good Laboratory Practice (GLP).

Article 10 Where the registration matters of a registered new cosmetic ingredient change, the registrant of the new ingredient shall submit corresponding documents to complete the change in accordance with the provision before the ingredient is put into use.

Where the filing matters of a filed new cosmetic ingredient change, the filing person of the new ingredient shall update them in a timely manner to ensure that the relevant information and documents on the information service platform are authentic and accurate.

Article 11 The specific technical requirements for registration and filing documents of new cosmetic ingredients, and the specific technical requirements for the change and update of new ingredient information, shall be formulated by the cosmetic technical review authority.

Article 12 Registrants, filing persons of new cosmetic ingredients, or domestic responsible persons shall keep samples of new ingredients on

息资料真实准确：

（一）化妆品新原料注册人、备案人或者境内责任人的法定代表人、联系方式等信息发生变化时，用户应当在信息服务平台上自行更新；

（二）化妆品新原料注册人、备案人或者境内责任人的其他基本信息、新原料安全风险监测和评价体系概述、境内责任人的授权范围和授权期限发生变化的，应当提交化妆品新原料注册人、备案人信息更新表，并按要求提交相关资料后完成相关信息资料的更新。

其中，境外注册人、备案人名称、地址发生变化的，应当提供由所在国（地区）政府主管部门或者有关机构出具的主体未发生变化的相关证明文件原件，无法提交原件的，应当提供由中国公证机关公证的或者由我国使（领）馆确认的复印件；境内责任人名称、地址发生改变的，应当提供我国政府主管部门或者有关机构出具的主体未发生变化的相关证明文件原件。

境内责任人授权范围改变的，新授权范围应当包括原授权范围；仅进行授权期限更新的，授权书其他内容不得改变。

境内责任人变更的，应当提交符合本规定第六条要求的授权书，以及拟变更境内责任人承担原境内责任人相关各项责任的承诺书。

第八条 化妆品新原料注册人、备案人申请化妆品新原料注册或者进行新原料备案的，应当提交以下资料：

（一）注册人、备案人、境内责任人的名称、地址、联系方式；

（二）新原料研制报告；

（三）新原料的制备工艺、稳定性及质量控制标准等研究资料；

（四）新原料安全评估资料。

化妆品新原料注册人、备案人应当结合新原料注册、备案资料相关技术信息，编制并提供化妆品新原料技术要求。技术要求应当包含基本信息、使用目的、安全使用量、注意事项、使用期限等内容。

第九条 化妆品新原料注册人、备案人提交的化妆品新原料毒理学、人体安全性报告应当由取得相关项目的检验检测机构资质认定（CMA）、取得相关项目的中国合格评定国家认可委员会（CNAS）认可、符合良好临床试验规范（GCP）或者符合良好实验室操作规范（GLP）的机构出具。

第十条 已注册化妆品新原料的注册事项发生变化的，新原料注册人应当在原料投入使用前按规定提交相应资料完成变更。

已备案新原料的备案事项发生变化的，新原料备案人应当及时进行更新，确保信息服务平台中的相关信息资料真实准确。

第十一条 新原料注册备案资料的具体技术要求和新原料信息变更更新的具体技术要求由化妆品技术审评机构制定。

第十二条 化妆品新原料注册人、备案人或者境内责任人应当留存新原料的样品备查。化妆品

file for inspection. When the cosmetic technical evaluation authority needs to inspect samples of new ingredients during technical evaluation or technical verification, registrants, filing persons, or domestic responsible persons shall provide samples as required in a timely manner.

Samples of new cosmetic ingredients shall have complete packaging and labels. The labels shall include information such as the name of the registrant, filing person, or domestic responsible person, the Chinese name of the ingredient, production date and period of use, and storage conditions.

Article 13 For registered and filed new cosmetic ingredients, registrants, filing persons, or domestic responsible persons shall collect and sort out the following information and documents in accordance with the relevant requirements of the safety monitoring period for new ingredients, and submit the annual safety monitoring report for new ingredients through the information service platform within 30 working days before the expiry of each full year of the safety monitoring period: (1) Information of cosmetic registrants, filing persons, and entrusted manufacturers that use the new ingredient; (2) Information of cosmetics produced with the new ingredient, including product name, product registration certificate number or filing certificate number, and production or import and sales volume of the products; (3) Information on sampling inspection, case filing and investigation, and product recall of cosmetics produced with the new ingredient; (4) Statistical analysis of adverse reactions of cosmetics produced with the new ingredient by cosmetic registrants and filing persons, and the measures taken.

Article 14 Where registrants, filing persons of new cosmetic ingredients, or domestic responsible persons find circumstances that shall be reported to the cosmetic technical evaluation authority as specified in the *Measures for the Administration of Cosmetics Registration and Filing* during the use of new ingredients, they shall collect and sort out information in a timely manner, such as basic information of the new ingredient, production or import, sales and use conditions, cause analysis of safety problems or emergencies, disposal measures taken, and handling results, and submit a safety risk control report for new cosmetic ingredients to the cosmetic technical evaluation authority through the information service platform.

Article 15 This Provision shall come into force on July 15, 2026. The *Announcement of the National Medical Products Administration on Issuing the Provision on the Administration of the Dossier for Registration and Filing of New Cosmetic Ingredients* (No. 31, 2021) shall be repealed simultaneously.

(2026-06-26)

技术审评机构在技术审评或者技术核查过程中需要查看新原料样品时，化妆品新原料注册人、备案人或者境内责任人应当及时按要求提供样品。

化妆品新原料的样品应当有完整的包装和标签，标签应当包括新原料注册人、备案人或者境内责任人名称、原料的中文名称、生产日期和使用期限、贮存条件等信息。

第十三条 对于已经注册、备案的化妆品新原料，化妆品新原料注册人、备案人或者境内责任人应当按照新原料安全监测期相关要求，收集、整理以下信息资料，于新原料安全监测每满1年前30个工作日内，通过信息服务平台报送新原料安全监测年度报告：

（一）使用新原料的化妆品注册人、备案人、受托生产企业信息；

（二）使用新原料生产的化妆品信息，包括产品名称，产品注册证书或者备案凭证编号，产品生产或者进口、销售数量等；

（三）使用新原料生产的化妆品被抽样检验、立案调查、召回情况；

（四）化妆品注册人、备案人对使用新原料生产的化妆品的不良反应统计分析及采取措施等情况。

第十四条 化妆品新原料注册人、备案人或者境内责任人发现新原料使用过程中存在《化妆品注册备案管理办法》规定应当向化妆品技术审评机构报告的情况，应当及时收集整理新原料基本信息、生产或者进口、销售、使用情况、安全性问题或者突发情况的原因分析、采取的处置措施和处理结果等信息，通过信息服务平台向化妆品技术审评机构提交化妆品新原料安全风险控制报告。

第十五条 本规定自2026年7月15日起实施。《国家药监局关于发布〈化妆品新原料注册备案资料管理规定〉的公告》（2021年第31号）同时废止。

（2026-06-26）

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

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

China Center for Medical Products International Exchange（CCMPIE）
中国药品国际交流中心
Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No.32, Xizhimen North Street, Haidian District, Beijing, 100082, PR.C. ,
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编:100082
Tel: 010-8221 2866
Email: ccfdie@ccfdie.org
Fax: 010-8221 2857
Website: www.ccfdie.org