NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

NMPA Announcement on Issuing the *Opinions on Deepening the Reform of Cosmetics Regulation and Promoting High-Quality Industry Development*

On November 17, 2025, the National Medical Products Administration (NMPA) issued the *Opinions on Deepening the Reform of Cosmetics Regulation and Promoting High-Quality Industry Development (hereinafter referred to as the "Opinions").*

The Opinions propose 24 reform measures across five key areas, aiming to further strengthen the cosmetics industry's quality and safety baseline, foster new productive forces, and promote high-quality industry development. These measures focus on encouraging innovation, optimizing registration and filing management, strengthening risk prevention and control throughout the entire supply chain, enhancing intelligent regulation, and aligning regulatory practices with international standards.

The Opinions state that by 2030, the legal and regulatory framework for cosmetics regulation will be more complete, the standards system more sound, technical support more robust, industrial innovation vitality stronger, risk prevention and control capabilities comprehensively enhanced, and the level of quality and safety significantly improved. By 2035, the cosmetics quality and safety regulatory system will reach an internationally advanced level, the industry's capacity for innovation and global competitiveness will be significantly enhanced, and regulatory modernization will be essentially achieved.

The release of the Opinions is an important measure by the NMPA to implement the strategic deployment of the Party Central Committee and the State Council on comprehensive deepening of reform and promoting high-quality development. It will better safeguard the people's demand for cosmetics and inject a strong impetus into the high-quality development of the cosmetics industry.

(November 17, 2025)

国家药监局发布《关于深化化妆品监管改革促进产业高质量发展的意见》

2025年11月17日，国家药监局发布《关于深化化妆品监管改革促进产业高质量发展的意见》（以下简称《意见》）。

《意见》围绕五个方面提出24项改革措施，通过鼓励创新、优化注册备案管理、强化全链条风险防控、提升智慧化监管水平、推动监管与国际接轨，进一步筑牢化妆品质量安全底线，培育新质生产力，助推化妆品产业高质量发展。

《意见》提出，到2030年，化妆品监管法律制度更加完善，标准体系更加健全，技术支撑更加有力，产业创新活力更加充沛，风险防控能力全面加强，质量安全水平显著提升。到2035年，化妆品质量安全监管体系达到国际先进水平，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。

《意见》的发布，是国家药监局贯彻落实党中央、国务院关于全面深化改革、推动高质量发展战略部署的重要举措，将更好保障人民群众用妆需求，为化妆品产业高质量发展注入强劲动力。

(2025-11-17)

NMPA's Opinions on Deepening the Reform of Cosmetics Regulation and Promoting High-Quality Industry Development [2025] No.18

To all provincial-level medical products administrations (including those of autonomous regions and municipalities directly under the central government, and Xinjiang Production and Construction Corps):

Cosmetics are important consumer products that meet people's demand for beauty and their aspiration for a high-quality life. In recent years, the drug regulatory authorities have actively promoted reforms in cosmetics regulation, accelerated the improvement of the cosmetics regulatory framework, strengthened the regulatory mechanisms, and innovated regulation approaches. As a result, China's cosmetics industry has experienced robust growth, and the quality and safety levels have continued to rise. To further coordinate high-quality development and high-level safety in the cosmetics sector, and thereby better meet the people's new expectations for a better life in the new era, the following opinions are proposed to deepen the reform of cosmetics

国家药监局关于深化化妆品监管改革促进产业高质量发展的意见 国药监妆〔2025〕18号

各省、自治区、直辖市和新疆生产建设兵团药品监督管理局：

化妆品是满足人民群众对美的需求和高品质生活向往的重要消费品。近年来，药品监管部门积极推进化妆品监管改革，加快完善化妆品监管法规体系，健全监管制度机制，创新监管方式方法，我国化妆品产业蓬勃发展，质量安全水平持续提升。为进一步统筹化妆品高质量发展和高水平安全，更好满足新时代人民群众对美好生活的新期盼，现就深化化妆品监管改革促进化妆品产业高质量发展提出以下意见。

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regulation and promote the high-quality development of the cosmetics industry.

I. General Requirements

Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, the Opinions fully implement the spirit of the 20th National Congress of the Communist Party of China and the 2nd, 3rd, and 4th Plenary Sessions of the 20th Central Committee, and fulfill the requirements for comprehensively deepening reform. Based on the new development stage and the implementation of the new development concept, the *Opinions* build a new development pattern, adhering to the path of scientific, legal, international, and modern regulatory development. In accordance with the requirements of "Stressing Political Awareness, Enhancing Supervision, Ensuring Safety, Promoting Development and Improving People's Well-Being", the *Opinions* focus on coordinating development with safety, vitality with order, quality with efficiency, and regulation with service. The purpose is to enhance the systematic, holistic and coordinated nature of regulation reform; deepen cosmetics regulation reform across the entire process; strengthen the safety foundation of cosmetics in an all-round manner; support high-quality development of the cosmetics industry across the full-chain; accelerate China's transformation from a major cosmetics producer to a leading cosmetics powerhouse; and effectively enhance the people's sense of fulfillment, happiness and security in the cosmetics sector.

By 2030, the legal and regulatory framework for cosmetics regulation will be more complete, the standards system more sound, technical support more robust, industrial innovation vitality stronger, risk prevention and control capabilities comprehensively enhanced, and the level of quality and safety significantly improved. By 2035, the cosmetics quality and safety regulatory system will reach an internationally advanced level, with a regulatory system, regulatory mechanisms, and regulatory approach that are better suited to the intrinsic needs of innovation and high-quality development. The industry's capacity for innovation and global competitiveness will be significantly enhanced, and regulatory modernization will be essentially achieved.

II. Intensifying Support for Innovation in the Cosmetics Industry

(1) Facilitating registration pathways for cosmetics with new efficacy claims. In response to new social consumption demands and emerging industry trends, the Opinions support the registration and filing of cosmetics with new efficacy claims, implement an immediate review upon submission, and introduce a pre-submission consultation mechanism for their registration. The Opinions will also adjust the cosmetics classification rules and catalogue.

(2) Encouraging the new cosmetics' first launch in China. In alignment with international high standards for trade and economic regulations, the *Opinions* will foster a "first-launch economy" in China's cosmetics sector. For international cosmetics products that are first launched in China, the requirement to submit marketing authorization documents from the country (region) of manufacture will be exempted, in accordance with regulations for products manufactured specifically for export to China.

(3) Promoting the development of the Aging Economy in cosmetics. The *Opinions* encourage enterprises to strengthen technological R&D for cosmetics designed for "silver-haired" consumers, and support cutting-edge fundamental research on skin-aging mechanisms. The *Opinions* support the development, application, and registration of cosmetics tailored to the characteristics and needs of the elderly population, addressing the diverse consumption demands of this demographic.

(4) Innovating cosmetics labeling management. In response to the demand for intelligent and green development in the cosmetics industry, the *Opinions* accelerate the implementation of electronic labeling for cosmetics. The *Opinions* will establish labeling and data management requirements for electronic labeling for cosmetics, achieving a digital upgrade, refined governance, and convenient services for label management.

(5) Innovating personalized service models. In response to the people's demand forpersonalized and precision consumption, the *Opinions* adhere to a demand-driven, safe, controlled, and regulated approach. The *Opinions* will explore personalized services for cosmetics and allow cosmetics registrants to provide on-site simplified mixing, repacking, and other services for registered ordinary cosmetics based on consumer needs at their

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、四中全会精神，落实全面深化改革要求，立足新发展阶段，贯彻新发展理念，构建新发展格局，坚持科学化、法治化、国际化、现代化的监管发展道路，按照"讲政治、强监管、保安全、促发展、惠民生"的要求，着力统筹发展与安全、活力与秩序、质量与效率、监管与服务，进一步增强监管改革的系统性、整体性和协调性，全过程深化化妆品监管改革，全方位筑牢化妆品安全底线，全链条支持化妆品产业高质量发展，加快推进我国从"制妆大国"向"制妆强国"的跨越，切实增进人民群众在化妆品领域的获得感、幸福感、安全感。

到2030年，化妆品监管法律制度更加完善，标准体系更加健全，技术支撑更加有力，产业创新活力更加充沛，风险防控能力全面加强，质量安全水平显著提升。到2035年，化妆品质量安全监管体系达到国际先进水平，监管体系、监管机制、监管方式更好适应产业创新与高质量发展的内在要求，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。

二、加大化妆品产业创新支持力度

（一）畅通新功效化妆品注册渠道。适应社会消费新需求和行业发展新趋势，支持新功效化妆品注册申报，对申报新功效化妆品即报即审。研究建立新功效化妆品注册申报前置咨询机制，适时调整化妆品分类规则与分类目录。

（二）鼓励化妆品新品在中国首发。对标国际高标准经贸规则，培育我国化妆品领域首发经济，对国际化妆品新品在中国首发上市的，参照专为向我国出口生产的相关规定，免于提交在生产国（地区）已上市销售的证明文件。

（三）促进化妆品银发经济发展。鼓励企业加强"银发族"化妆品的技术研发，开展皮肤衰老机理等前沿基础研究。支持适合老年群体特点和需求的化妆品开发应用和注册备案，满足老年群体多样化消费需求。

（四）创新化妆品标签管理。适应化妆品产业智能化、绿色化发展需求，加快实施化妆品电子标签，制定化妆品电子标签的标注及数据管理要求，实现标签管理的数字化升级、精细化治理和便利化服务。

（五）创新个性化服务方式。适应公众个性化、精准化消费需求，坚持需求导向、安全可控、规范有序原则，探索化妆品个性化服务路径，允许化妆品备案人根据消费者需求，在经营场所提供已备案普通化妆品的现场简易调配、分装等服务。

（六）加大产业扶持力度。鼓励省级药品

distribution premises.

(6) Increasing industry support. Provincial drug regulatory departments are encouraged to actively seek government support and coordinate with relevant departments to introduce policies that support the cosmetics industry. This will create a favorable environment for industry innovation, support the green and low-carbon development of the sector, and empower the rise of brands. Efforts will be made to foster the growth of nationally competitive, internationally recognized cosmetics brands.

III. Enhancing the Efficiency of Cosmetics Registration and Filing Management

(7) Supporting technological innovation in cosmetic ingredients. The *Opinions* improve the classified management and technical evaluation system for new ingredients; explore the establishment of ingredient nomenclature rules that fit China's national conditions and align with international practice; focus on developing standards for high-use-frequency ingredients, ingredients with prominent safety risks, and ingredients derived from plant resources with Chinese characteristics. The *Opinions* build a mechanism for R&D–review collaboration to provide end-to-end services of early engagement, process guidance and dynamic optimization for eligible new ingredients.

(8) Optimizing cosmetics registration and filing documentation. While ensuring cosmetics quality and safety and meeting regulatory requirements, the *Opinions* allow products with similar formulas but differences in components such as colorants or fragrances (in terms of type or content) to share a Material Safety Data Sheet for registration and filing under the same brand. For cosmetics that require re-registration due to changes in the production premises, the original registration and filing technical documentation may be used, except for the microbiological and physicochemical Certificate of Analysis. The *Opinions* strengthen the primary responsibility of cosmetics registrants and filing entities for quality and safety, and adjust the storage of cosmetic raw material safety-related information to be archived by enterprises for reference.

(9) Improving the quality and efficiency of technical review. The *Opinions* explore and establish a "NMPA–provincial administration" coordinated review mechanism and delegate certain technical review tasks for special cosmetics to capable provincial drug regulatory departments. Registration changes in special cosmetics will be subject to categorized management: for high-risk changes, the review period will be shortened from 90 to 60 working days; for low-risk changes, to 45 working days. For changes that do not involve safety or efficacy claims, registrants will be permitted to maintain product registration information on their own.

(10) Optimizing the safety assessment system. The *Opinions* strengthen research and innovation in cosmetics safety assessment technologies, promote the use of advanced assessment techniques and strategies, and continuously improve the technical guidelines to enhance the scientific rigor, precision, and applicability of safety assessments. The *Opinions* guide and urge cosmetics companies to strengthen the concept of safety assessment, implement full-life-cycle management responsibilities for products, and continually improve the ability to ensure product quality and safety.

(11) Optimizing efficacy claims management. Except for efficacy claims such as spot corrector and whitening, sunscreen, and preventing hair loss, the *Opinions* allow cosmetics registrants and filing entities to independently select appropriate efficacy evaluation methods for efficacy claims. The *Opinions* allow similar products within the same brand that differ only in the type or content of ingredients such as colorants, fragrances, or preservatives to share test data of efficacy claims. The *Opinions* support the associations of the cosmetics industry and other social organizations in strengthening industrial self-discipline, focusing on key efficacy categories of general industry concern, researching guidelines for cosmetics efficacy claims, and guiding the standardization of labeling and claim language.

IV. Improving the Regulatory Mechanism for Production and Marketing of Cosmetics

(12) Advancing graded and classified regulation of enterprises. Local drug regulatory authorities at all levels are encouraged to establish and improve a graded and classified management system for production and marketing of cosmetics based on risk management principles. According to key

监管部门积极争取政府支持，协调相关部门出台化妆品产业扶持政策，营造良好的产业创新环境，支持行业绿色低碳发展，通过政策赋能推动品牌崛起，培育具有国际竞争力的民族品牌化妆品。

三、提升化妆品注册备案管理效能

（七）支持化妆品原料技术创新。完善新原料分类管理及技术评价体系，探索建立符合国情且与国际接轨的原料命名规则，聚焦行业使用广、安全风险高及中国特色植物资源原料制定标准。构建研发审评协同机制，对符合条件的新原料设立前置咨询通道，提供早期介入、过程指导、动态优化的全流程服务。

（八）优化化妆品注册备案资料。在保障化妆品质量安全和满足监管需求的前提下，允许仅着色剂、香精等成分的种类或者含量上存在差异的配方体系近似的同一品牌产品，注册备案时共用产品安全性技术资料。对因生产场地变化需重新注册备案的化妆品，除微生物和理化检验报告外，允许使用原注册备案技术资料。强化化妆品注册人备案人质量安全主体责任，将化妆品原料安全相关信息调整为企业自行存档备查。

（九）提高技术审评质效。探索建立"国家局一省局"联合审评协同机制，委托具备能力的省级药品监管部门承担特殊化妆品部分技术审评工作。对特殊化妆品变更事项分类管理，将高风险、低风险变更事项审评时限从90个工作日分别缩短至60个工作日、45个工作日，不涉及安全性、功效宣称的变更事项允许注册人自行维护产品注册信息。

（十）优化安全评估制度。加强化妆品安全评估技术研究与创新，推广应用先进评估技术和策略，持续完善化妆品安全评估技术指南，提升评估工作的科学性、精准性和应用性。引导督促化妆品企业强化安全评估理念，落实产品全生命周期管理责任，不断提高产品质量安全保障能力。

（十一）优化功效宣称管理。除祛斑美白、防晒、防脱发功效外，允许化妆品注册人备案人自主选择功效宣称评价试验方法进行功效宣称评价。允许仅着色剂、香精、防腐剂等成分的种类或者含量上存在差异的配方体系近似的同一品牌产品，共享功效宣称评价试验数据。支持化妆品行业协会等社会组织加强行业自律，聚焦行业普遍关注的重点功效类别，研究化妆品功效宣称指引，引导规范标签宣称用语。

四、完善化妆品生产经营监管机制

（十二）推动企业分级分类监管。鼓励地方各级药品监管部门按照风险管理的原则，建立健全化妆品生产经营主体的分级分类管理机

factors such as enterprises' quality management systems and risk prevention and control capabilities, the *Opinions* assess risk grades scientifically to allocate regulatory resources more rationally and improve regulatory efficiency effectively.

(13) Optimizing production quality management. The *Opinions* carry out in-depth actions to enhance the production quality management systems of cosmetics manufacturers, exploring the optimization of production management systems. The goal is to comprehensively improve the operational effectiveness of the enterprises' quality management systems and their ability to ensure product quality and safety. Provincial drug regulatory authorities are encouraged to explore requirements for product release from off-site warehouses operating under the same manufacturing quality management system as the manufacturing site, and quality management requirements that adapt to intelligent cosmetics manufacturing. Efforts will be made to establish a professional title evaluation system for quality and safety experts in cosmetics research and development, production, testing and analysis, and safety and efficacy evaluation.

(14) Strengthening regulation of online business distribution. The *Opinions* improve mechanisms for "governing the internet via the internet" and continuously optimize the national cosmetics online business distribution monitoring platform to enhance risk identification and monitoring effectiveness. The *Opinions* hold e-commerce platforms accountable for managing operators within their platforms, continuously strengthen regulatory collaboration and risk-sharing mechanisms, and promote the coordination between administrative regulation and platform governance. This will help identify and resolve potential safety risks of cosmetics. For typical illegal behaviors such as unregistered products, illegal additives, and operators self-compounding cosmetics, the *Opinions* strengthen key monitoring, thereby improving the quality and safety of cosmetics online business distribution.

(15) Strengthening adverse reaction monitoring and evaluation. The *Opinions* improve the cosmetics adverse reaction monitoring system, upgrade the monitoring platform's functionality, and strengthen data quality management to improve the accuracy and usability of monitoring data. The *Opinions* promote the sharing of national adverse reaction monitoring data, ensure that cosmeticsregistrants and filing entities take responsibility for analysis and evaluation, and further strengthen the deep analysis, scientific evaluation, and risk assessment of monitoring data. This will promote the conversion and application of evaluation results.

(16) Enhancing registration and filing extended regulation. Provincial drug regulatory authorities are encouraged to strengthen the authenticity audit of registration and filing data based on the needs of cosmetics registration and filing. Explore extended inspections to include testing agencies and other relevant entities, and work towards building a full-chain risk prevention and control system.

V. Strengthening Technical Support for Cosmetics Regulation

(17) Strengthening the regulatory team and capacity building. The *Opinions* strengthen professional technical capacity in cosmetics review, optimize the structure of cosmetics inspector teams, and enhance systematic training, professional management, and scientific performance evaluation for review and inspection personnel. Provincial drug regulatory authorities are encouraged to strengthen exchanges and cooperation, enhance resource sharing, information interconnection, and regulatory collaboration, and actively explore innovative regulatory models. Provincial drug regulatory authorities are encouraged to actively participate in special cosmetics registration, pre-submission consultations for new ingredient registrations, and other related work.

(18) Improving the standard system. The *Opinions* accelerate the establishment of a scientific, unified, authoritative, and efficient system of cosmetics standard management system and the development of plans for cosmetics standards. The *Opinions* speed up the development of mandatory national standards with a focus on safety, and strengthen the binding force of basic safety standards. Focusing on key areas and weak links such as ingredient safety control, safety and efficacy evaluation, and the application of emerging technologies, the Opinions precisely fill gaps in the standard system, providing standardized support for the regulated development of the

制。依据企业的质量管理体系、风险防控能力等关键要素，科学评估风险等级，合理配置监管资源，有效提升监管效能。

（十三）优化生产质量管理。深入开展化妆品企业生产质量管理体系提升行动，探索优化生产管理制度，全面提升企业生产质量管理体系运行效能与产品质量安全保障能力。鼓励省级药品监管部门探索与生产场地执行同一生产质量管理体系外设仓库的产品放行管理要求和适应化妆品智能化生产的质量管理要求，推动建立化妆品研发与生产、检测与分析、安全与功效评价等质量安全专业人才的职称评定体系。

（十四）强化网络经营监管。健全"以网管网"监管机制，持续优化国家化妆品网络经营监测平台功能，提高风险识别能力和网络监测效能。压实电商平台对平台内经营者管理责任，持续强化监管协作和风险共治机制，推动行政监管和平台治理协同发力，排查化解化妆品安全风险隐患。对未经注册备案、非法添加禁用物质、经营者自行配制等典型违法行为加强重点监测，提升网络经营化妆品的质量安全水平。

（十五）强化不良反应监测与评价。完善化妆品不良反应监测体系，优化升级不良反应监测平台功能，强化数据质量管理，提升监测数据的准确性和可利用性。推动国家不良反应监测数据共享，落实化妆品注册人备案人分析评价的主体责任，进一步强化监测数据的深度分析、科学评价与风险研判，推动评价结果的转化运用。

（十六）加强注册备案延伸监管。推动省级药品监管部门根据化妆品注册备案工作需要加强注册备案数据的真实性核查，探索开展对检验机构等的延伸检查，推动构建全链条风险防控体系。

五、强化化妆品监管技术支撑保障

（十七）加强监管队伍和能力建设。充实化妆品审评专业技术力量，优化化妆品检查员队伍结构，强化化妆品审评和检查员队伍系统化培训、专业化管理和科学化考核。鼓励省级药品监管部门之间深化交流协作，加强资源共享、信息互通与监管协同，积极探索监管模式创新。鼓励省级药品监管部门积极参与特殊化妆品注册、化妆品新原料注册备案前置咨询等工作。

（十八）完善标准体系建设。加快推进科学、统一、权威、高效的化妆品标准管理体系，研究制定化妆品标准建设规划。加速推进以保障安全为核心的强制性国家标准建设，强化基础安全标准的约束力。聚焦原料安全控制、安全与功效评价、新兴技术应用等重点领

industry and improvements in quality and safety.

(19) Deepening regulatory science research. The *Opinions* fully utilize regulatory science innovation research bases to focus major research tasks on key areas such as safety assessment, innovative products and ingredients, and risk early warning. The *Opinions* improve the mechanism for the transformation and application of regulatory scientific research achievements, accelerate the development of new regulatory tools, standards, and methodologies, and enhance the scientific and modern level of regulation.

(20) Strengthen regulatory digital-informatization. The *Opinions* further enhance the intelligence regulation capabilities for cosmetics, promote the digitalization of the entire cosmetics regulatory business and process, ensure the full online handling of government affairs related to enterprises, optimize and upgrade the cosmetics regulatory APP, and improve the effectiveness of grassroots regulation and public science outreach services. The *Opinions* improve the information records of cosmetics registrants and filing entities, strengthen data collection and governance, advance scenario applications, and fully utilize the role of archival data in regulation. Provincial drug regulatory authorities are encouraged to accelerate the transformation to intelligence regulation, strengthen the application research of artificial intelligence in cosmetics registration, production, and distribution regulation, and improve the efficiency of regulatory work.

VI. Promoting the Alignment of Cosmetics Regulation with International Standards

(21) Deepening international exchange and cooperation. The NMPA actively participates in the development of technical documents and regulatory coordination under international cosmetics regulatory cooperation frameworks, and establishes and improves a regular mechanism for tracking, assessing, and responding to international regulatory dynamics. The NMPA actively promotes the convergence, coordination, and trust of cosmetics regulation. The associations of the cosmetics industry are encouraged to support the "go-global" efforts of domestic cosmetics and help the international development of China's cosmetics industry.

(22) Advancing alignment of the standards to the international ones. The NMPA strengthens research on international cosmetics standards, accelerates the transformation and application of internationally accepted standards, and promotes the alignment of domestic standards with internationally advanced levels. The NMPA actively participates in and promotes the initiation, research, and formulation of international standards to enhance China's influence and voice in the field of international cosmetics standards.

(23) Accelerating the reduction and exemption of animal testing. Following the principles of "reduce, replace, optimize", the NMPA accelerates efforts to reduce reliance on animal testing for cosmetics, starting with areas such as perming products, non-oxidative hair dyes, and the use of new ingredients during monitoring periods, then gradually implements animal testing exemptions. The NMPA adheres to the principle of "replace wherever possible" and accelerates the development, transformation, and application of alternative animal testing methods.

(24) Optimizing the management mechanism for permitted ingredients. The NMPA establishes a dynamic updating mechanism for standards related to preservatives, sunscreens, colorants, hair dyes, etc., and supports the inclusion of ingredients that have been scientifically evaluated by international authoritative bodies and have a history of safe use abroad into the domestic permitted ingredients list in a timely manner.

At all levels, drug regulatory authorities shall ensure that the leadership of the Party is firmly embedded throughout the entire process of deepening cosmetics regulation reforms. They shall fully recognize the significant role of these reforms in promoting high-quality industry development and high-level safety. The NMPA shall resolutely implement the "four strictest" requirements, with a strong sense of responsibility and mission, closely integrate the specific circumstances of each region, and comprehensively implement the reform measures and work requirements outlined in this opinion to ensure that all reform tasks are fully carried out and achieve tangible results.

National Medical Products Administration

November 14, 2025

(November 17, 2025)

域和薄弱环节，精准填补标准体系空白，为产业规范发展和质量安全提升提供标准化支撑。

（十九）深化监管科学研究。充分发挥化妆品监管科学创新研究基地作用，围绕安全评估、创新产品与原料、风险预警等关键领域，布局重大科研攻关任务。完善监管科学研究成果转化应用机制，加快研发监管新工具、新标准、新方法，提升监管的科学化、现代化水平。

（二十）加强监管信息化建设。进一步提升化妆品智慧监管能力，推动化妆品监管全业务全流程数字化，涉企政务事项全环节全流程在线办理，优化升级化妆品监管APP，提升服务基层监管效能和公众科普服务水平。完善化妆品注册人备案人信息档案，强化数据汇集与治理，推进场景应用，充分发挥档案数据在监管中的作用。鼓励各省级药品监管部门加快智慧化转型，加强人工智能在化妆品备案、生产和经营监管等领域的应用研究，提升监管工作效率。

六、推动化妆品监管与国际接轨

（二十一）深化国际交流与合作。深度参与国际化妆品监管合作组织框架下的技术文件制定与监管协调，建立健全国际化妆品监管动态的常态化跟踪、研判与响应机制。积极推动化妆品监管趋同、协调和信赖，鼓励化妆品行业协会等社会组织服务国产化妆品"出海"，助力中国化妆品产业国际化发展。

（二十二）提升标准国际化水平。深化国际化妆品标准体系研究，加快国际通行标准转化与应用，推动国内标准与国际接轨。积极参与并推动国际标准的立项、研究与制定，增强我国在国际化妆品标准领域的影响力和话语权。

（二十三）加快推进动物试验减免。遵循"减少、代替、优化"原则，加快推动减少化妆品动物试验依赖，从烫发、非氧化型染发和使用监测期新原料的化妆品等着手，逐步推行动物试验豁免。坚持"能转尽转"，加速动物替代试验方法开发、转化和应用。

（二十四）优化准用原料管理机制。建立防腐剂、防晒剂、着色剂、染发剂等的标准动态更新机制，支持将经国际权威机构科学评估、具有国外安全使用历史的原料，及时纳入我国准用原料目录。

各级药品监管部门要把坚持和加强党的领导贯穿于深化化妆品监管改革的各方面和全过程，深刻认识深化化妆品监管改革对推动产业高质量发展和高水平安全的重大意义，坚决贯彻"四个最严"要求，以高度的责任感和使命感，紧密结合本地区实际，全面落实本意见提出的各项改革举措和工作要求，确保各项改革任务落实到位、取得成效。

国家药监局

2025年11月14日

(2025-11-17)

Policy Interpretation of the *NMPA's Opinions on Deepening the Reform of Cosmetics Regulation and Promoting High-Quality Industry Development*

To thoroughly implement the important instructions of General Secretary Xi Jinping on drug regulation and industrial development, further coordinate high-quality development and high-level safety in the cosmetics sector, and thereby better meet the people's new expectations for a better life in the new era, the NMPA has issued the *NMPA's Opinions on Deepening the Reform of Cosmetics Regulation and Promoting High-Quality Industry Development (hereinafter referred to as the Opinions)*. The key points are interpreted as follows.

I. Drafting Background of the *Opinions*

The CPC Central Committee and the State Council attach great importance to cosmetics regulation and industrial development. General Secretary Xi Jinping has emphasized that the people's aspiration for a better life is the goal of our endeavors. As a vital component of the big health industry, the cosmetics sector serves as a key field for fulfilling people's aspirations for a better life, reflecting consumption vitality and cultural confidence. The 20th CPC National Congress report outlined the promotion of the Healthy China initiative, accelerated innovation-driven development strategy, and laid out a strategic path and development roadmap centered on achieving self-reliance and self-strengthening in science and technology, providing strong and enduring momentum for the innovative, high-quality development of the cosmetics industry.

Since 2018, drug regulatory authorities have adhered to political leadership, a problem-solving approach, China's national conditions, international perspectives, reform and innovation, and scientific development. They have vigorously promoted the development of the regulatory system and standards system for cosmetics, improved regulatory mechanisms, innovated regulatory approaches, and carried out comprehensive safety governance. As a result, the overall level of cosmetics quality and safety has continued to rise, and the industry has experienced robust growth. As of the end of October 2025, there were more than 20,000 cosmetics registrants and filing entities in China, 46,000 registered special cosmetics, 2,291,000 filed ordinary cosmetics, and 327 registered or filed new cosmetic ingredients. According to statistics from the China Association of Fragrance Flavour and Cosmetic Industries, China's cosmetics market transaction value exceeded 1 trillion yuan in 2024, making it the world's largest cosmetics consumption market. At the same time, China's cosmetics industry remains large in scale but not yet strong, facing underlying structural challenges such as a low degree of industrial intensification, shortcomings in quality management systems among some enterprises, limited capacity for independent innovation, and inadequate core competitiveness.

Based on a comprehensive review of existing policies, in-depth investigation, and extensive consultation with all parties, the NMPA drafted the *Opinions* to enhance the systematic, holistic and coordinated nature of regulation reform; deepen cosmetics regulation reform across the entire process; strengthen the safety foundation of cosmetics in an all-round manner; support high-quality development of the cosmetics industry across the full-chain; accelerate China's transformation from a major cosmetics producer to a leading cosmetics powerhouse; and effectively enhance the people's sense of fulfillment, happiness and security in the cosmetics sector.

II. Overall Considerations and Main Content of the *Opinions*

The *Opinions* are grounded in the fundamental nature of cosmetics as essential consumer products and focus on meeting the public's aspirations for a better life and aligning with the central theme of deepening regulation reform and promoting high-quality industry development. Guided by the principles of "high-quality development, high-level safety, high-efficiency governance, and high-standard opening-up," and while ensuring the stability and continuity of regulatory policies, the *Opinions* respond to the urgent needs of industrial innovation and put forward a series of reform measures for cosmetics regulation.

《国家药监局关于深化化妆品监管改革促进产业高质量发展的意见》政策解读

为深入贯彻落实习近平总书记关于药品监管和产业发展的重要指示批示精神，进一步统筹化妆品高质量发展和高水平安全，更好满足新时代人民群众对美好生活的新期盼，国家药监局发布了《国家药监局关于深化化妆品监管改革促进产业高质量发展的意见》（以下简称《意见》），现就有关内容予以解读。

一、《意见》的起草背景

党中央、国务院高度重视化妆品监管和产业发展。习近平总书记强调，人民对美好生活的向往就是我们的奋斗目标。化妆品行业作为大健康产业的重要组成部分，是满足人民群众美好生活需要、彰显消费活力与文化自信的重要领域。党的二十大报告提出"推进健康中国建设""加快实施创新驱动发展战略"，规划了以科技自立自强为核心的战略路径与发展路线，为化妆品行业的创新高质量发展注入了强大而持久的动力。

自2018年以来，药品监管部门坚持政治引领、坚持问题导向、坚持立足国情、坚持国际视野、坚持改革创新、坚持科学发展，全力推进化妆品监管法规制度建设和标准体系建设，健全监管机制、创新监管方式，深入开展安全治理，化妆品质量安全水平持续提升，产业蓬勃发展。截至2025年10月底，我国化妆品注册人备案人企业2万余家，注册的特殊化妆品4.6万个，备案的普通化妆品229.1万个，注册备案化妆品新原料327个。据中国香妆协会统计，2024年中国化妆品市场交易额达1万亿以上，已成为全球第一大消费市场。同时，我国化妆品产业仍大而不强，存在产业集约化程度不高、部分企业质量体系尚不完善、自主创新能力有待提升、核心竞争力不足等深层次矛盾和问题。

国家药监局在全面梳理政策、深入调查研究、广泛听取各方意见的基础上，起草了《意见》，旨在进一步增强监管改革的系统性、整体性和协调性，全过程深化化妆品监管改革，全方位筑牢化妆品安全底线，全链条支持化妆品产业高质量发展，加快推进我国从"制妆大国"向"制妆强国"的跨越，切实增进人民群众在化妆品领域的获得感、幸福感、安全感。

二、《意见》的总体考虑和主要内容

《意见》立足化妆品作为人民群众重要消

The *Opinions* are divided into six parts. The first part specifies the overall requirements, sets out the guiding ideology and main goals of the reform, and proposes that by 2030 the legal system for cosmetics regulation will be more complete, the standards system more sound, technical support more robust, industrial innovation vitality stronger, risk prevention and control capabilities comprehensively enhanced, and the level of quality and safety significantly improved. By 2035, the cosmetics quality and safety regulatory system will reach an internationally advanced level, the industry's capacity for innovation and global competitiveness will be significantly enhanced, and regulatory modernization will be essentially achieved. The second through sixth parts set out 24 reform measures across five areas.

1. Encouraging innovation and fostering new, high-quality productive forces. Facilitate registration pathways for cosmetics with new efficacy claims and implement a system of immediate review upon submission; encourage international innovative cosmetics to be launched first in China by exempting the requirement for supporting documents of overseas marketing authorization; promote the "silver economy" by supporting R&D of products targeted at the elderly population; and advance innovative approaches to cosmetics labeling and personalized service models.

2. Improving quality and efficiency, and optimizing registration and filing management. Simplify registration and filing dossiers, allowing products with similar formulations to share part of the technical documentation; shift ingredient safety information to enterprise-level archiving for inspection; implement classified management for changes to special cosmetics and shorten review timelines.

3. Ensuring scientific regulation and strengthening risk prevention and control. Implement graded and classified regulation of enterprises and rationally allocate regulatory resources; strengthen regulation of online business distribution, improve mechanisms for "governing the internet via the internet", and ensure platforms fully assume their responsibilities; enhance the adverse reaction monitoring system and strengthen analysis, evaluation and application of monitoring data; promote extended inspections associated with registration and filing to build a whole-chain risk prevention and control system.

4. Providing technical support and consolidating the regulatory foundation. Strengthen the management and training of review and inspection teams; establish a "NMPA–provincial administration" coordinated review mechanism; improve the standards system and accelerate the development of mandatory national standards; deepen regulatory science research and promote the R&D and application of new tools and new standards; enhance intelligent regulation and accelerate the application of artificial intelligence technologies in regulatory activities.

5. Promoting regulatory coordination and enhancing international competitiveness. Accelerate the adoption and implementation of internationally accepted standards and actively participate in the development of international standards; progressively expand exemptions from animal testing and expedite the development, adoption, and application of alternative methods; and establish a dynamic mechanism for updating positive lists of permitted ingredients to broaden the space for enterprise innovation.

III. Considerations for Supporting Industrial Innovation

1. Supporting technological innovation in cosmetic ingredients. Cosmetic ingredients form the fundamental basis of product safety and efficacy, and the level of ingredient innovation directly determines the quality and level of industrial development. To stimulate innovation vitality in cosmetic ingredients, at the beginning of this year, the NMPA issued the Several *Provisions* on Supporting Innovation in Cosmetic *Ingredients*, introducing nine supporting measures for ingredient R&D and registration/filing. On this basis, the *Opinions* further propose optimization measures: improve the classified management and technical evaluation system for new ingredients; explore the establishment of ingredient nomenclature rules that fit China's national conditions and align with international practice; strengthen standards guidance by focusing on developing standards for

费品的基本特点，着眼满足人民对美好生活的向往，紧扣深化监管改革与促进产业高质量发展主线，围绕“高质量发展、高水平安全、高效能治理、高标准开放”原则，在保持监管政策稳定性、连续性基础上，适应产业创新发展的迫切需要，研究提出一系列化妆品监管改革举措。《意见》分为六部分。第一部分是总体要求，明确了改革的指导思想和主要目标，提出到2030年，化妆品监管法律制度更加完善，标准体系更加健全，技术支撑更加有力，产业创新活力更加充沛，风险防控能力全面加强，质量安全水平显著提升。到2035年，化妆品质量安全监管体系达到国际先进水平，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。第二至第六部分提出了5方面24条改革举措。

一是鼓励创新，培育新质生产力。畅通新功效化妆品注册渠道，实行即报即审；鼓励国际化妆品新品在中国首发，免于提交境外上市销售证明；促进银发经济，支持针对老年群体的产品研发；创新化妆品标签管理、个性化服务方式等。

二是提质增效，优化注册备案管理。简化注册备案资料，允许配方近似产品共用部分技术资料；将原料安全信息调整为企业存档备查；对特殊化妆品变更事项实施分类管理，压缩审评时限。

三是科学监管，强化风险防控。实施企业分级分类监管，合理配置监管资源；强化网络经营监管，健全“以网管网”机制，压实平台责任；完善不良反应监测体系，强化监测数据的分析、评价与应用；推动注册备案延伸检查，构建全链条风险防控体系。

四是技术保障，夯实监管基础。强化审评和检查员队伍的管理与培训；建立“国家局一省局”协同审评机制；完善标准体系，加快建设强制性国家标准；深化监管科学研究，推动新工具、新标准的研发与应用；提升智慧化监管水平，加快人工智能技术在监管中的应用。

五是监管协同，提升国际竞争力。加快国际通行标准转化实施，积极参与国际标准制定；逐步推行动物试验豁免，加速替代方法的开发、转化和应用；建立准用原料动态更新机制，拓宽企业创新空间。

三、支持产业创新方面有哪些考虑

一是支持化妆品原料技术创新。化妆品原料是产品安全与功效的核心基础，原料创新水平直接决定了产业发展的质量与高度。为激发原料

high-use-frequency ingredients, ingredients with prominent safety risks, and ingredients derived from plant resources with Chinese characteristics; and build a mechanism for R&D–review collaboration to provide end-to-end services of "early engagement, process guidance and dynamic optimization" for eligible new ingredients, thereby improving the quality of R&D and submission.

2. Facilitating registration pathways for cosmetics with new efficacy claims. With the rapid development of the economy and society and the continuous improvement of people's living standards, consumer demand for cosmetics has been rising, and expectations for new efficacy claims and new products are increasing day by day. At the same time, enterprises have a strong willingness for innovative development and hope to enhance product appeal through developing cosmetics with new efficacy claims and achieving differentiated market positioning. The pursuit of broader efficacy claims and expanded product categories has become a new driving force for the development of the cosmetics industry. However, R&D of cosmetics with new efficacy claims is difficult and costly and involves significant uncertainty. Enterprises urgently need systematic, scientific, and rational policy guidance and technical guidance during the R&D process. In view of the industry's development needs, the *Opinions* propose that the NMPA will establish dedicated review pathways for cosmetics with new efficacy claims, implement a system of immediate review upon submission, and introduce a pre-submission consultation mechanism for their registration. While strengthening service and guidance for enterprises, the review and approval procedures will be optimized to better meet emerging consumer demands and evolving industry trends. On this basis, the *Opinions* support innovative industry development by adjusting the cosmetics classification rules and catalogue and streamlining certain management requirements for some products.

3. Encouraging the new cosmetics' first launch in China. To foster a "first-launch economy" in China's cosmetics sector, and on the premise of strictly ensuring product safety, the Opinions specify that eligible international new cosmetic products may be exempt from submitting overseas marketing authorization documents, effectively removing the "time barrier." This opens up a "fast track" for trendy international products to enter the Chinese market more quickly, enabling consumers to experience the latest and highest-quality beauty products from around the world at the earliest opportunity. It will also effectively stimulate consumption vitality and promote a shift in domestic beauty consumption from "basic needs" to "quality upgrading".

IV. Better Addressing Emerging Consumer Needs

With the increasing aging population in China, demand for cosmetics among the elderly population is rising and becoming increasingly diversified. The Fourth Plenary Session of the 20th CPC Central Committee has outlined plans for developing the silver economy during the 15th Five-Year Plan period. The *Opinions* identify the promotion of the cosmetics-related silver economy as a key reform direction, encouraging and supporting the industry to address and meet the beauty needs of the elderly population and to advance the R&D and innovation of related products. The *Opinions* explicitly encourage enterprises to strengthen technological R&D for cosmetics designed for "silver-haired" consumers, and support cutting-edge fundamental research on skin-aging mechanisms to provide a scientific foundation for technological innovation. At the same time, the *Opinions* support the development of cosmetics tailored to the characteristics and needs of the elderly population and, on the premise of ensuring safety and efficacy, accelerate their registration, filing, and marketing process. This policy direction aligns with the national strategy for the silver economy. It not only demonstrates a strong commitment to meeting the beauty needs of the elderly population but also opens up a new growth space for the cosmetics industry. As the potential of the "silver economy" continues to be unleashed, cosmetics specially developed for the elderly population are expected to become an important track for innovative industrial development, fostering a group of silver-focused cosmetic brands with Chinese characteristics and achieving a win-win

创新活力，国家药监局于今年初出台了《支持化妆品原料创新若干规定》，推出支持原料研发与注册备案的9条措施。在此基础上，《意见》进一步提出优化方案：完善新原料分类管理与技术评价体系，探索建立符合国情、对接国际的原料命名规则；加强标准引领，重点围绕使用频率高、安全风险突出以及中国特色植物资源等类别原料推动标准制定；构建研发审评协同机制，对符合条件的新原料提供"早期介入、过程指导、动态优化"的全流程服务，提升研发与申报质量。

二是畅通新功效化妆品注册渠道。随着经济社会的快速发展和人民生活水平的不断提高，公众对化妆品的消费需求持续提升，对新功效、新产品的期待与日俱增。同时，企业也有强烈的创新发展意愿，希望通过研制新功效化妆品，实现差异化运营，从而提升产品吸引力。追求更多功效、更多品类，成为推动化妆品行业发展的新动力。但新功效化妆品研发难度大、投入成本高，存在较大的不确定性，企业在研发过程中迫切需要系统、科学、理性的政策引导和技术指导。考虑行业发展实际，《意见》提出，国家药监局将对新功效化妆品设置专门审评通道，实施即报即审，并建立新功效化妆品注册申报前置咨询机制，在加强对企业服务指导的同时，优化审评审批程序，着力适应社会消费新需求和行业发展新趋势。在此基础上，通过调整化妆品分类规则与分类目录，简化部分产品管理要求，支持产业创新发展。

三是鼓励化妆品新品在中国首发。为培育我国化妆品领域首发经济，在严格保证产品安全的基础上，《意见》明确，允许符合相关要求的国际化妆品新品免于提交已上市销售许可证明文件，有效破除"时间门槛"。既为国际新潮产品开辟了"快速通道"，能够以更快的速度登陆中国市场，又能够让消费者第一时间体验到全球最新、最优质的美妆产品，同时还能有效激发消费活力，推动国内美妆消费从"基础需求"向"品质升级"转变。

四、如何更好地满足公众消费新需求

随着我国人口老龄化程度持续加深，老年群体对化妆品的需求日益增长且日趋多元化。党的二十届四中全会对"十五五"期间发展银发经济作出部署。《意见》将促进化妆品银发经济发展作为重要改革方向，引导和支持产业关注并满足老年群体对美的追求，推动相关产品研发与创新。《意见》明确，鼓励企业加强"银发族"化妆品的技术研发，支持开展皮肤衰

situation in both social and economic benefits.

To meet the needs of intelligent and green development in the cosmetics industry, the *Opinions* explicitly call for accelerating the implementation of electronic labeling for cosmetics. The NMPA plans to launch pilot programs for electronic cosmetics labeling in certain provinces (municipalities) starting from February 2026. The application of electronic labels will diversify how labeling information is presented. By simply scanning a code, consumers will be able to access and fully understand product information. Features such as page zooming and audio playback will allow label content to be displayed more clearly and vividly, significantly improving legibility and ease of reading. This will help meet the needs of elderly users as well as different demographic groups, and enhance consumers' overall experience and sense of fulfillment. The use of electronic labels can also streamline the content required on physical labels, allowing product packaging to become cleaner, more concise, and more visually appealing. Enterprises will be able to update electronic label content via information systems, enabling refined and dynamic management of labeling information, effectively avoiding resource waste from reprinting labels and thereby achieving energy saving, burden reduction, and cost-efficiency.

In addition, to respond to personalized and precision consumption demand, the *Opinions* propose innovating personalized service models. The NMPA has already initiated the second phase of pilot work on personalized cosmetics services.

V. New Measures to "Strengthen Safety and Safeguard the Bottom Line"

1. Comprehensively enhancing enterprise quality management levels. The effective implementation of cosmetics Good Manufacturing Practice (GMP) systems is essential for ensuring enterprises' quality management level. The *Opinions* accurately position the "golden key" of raising enterprises' quality management level and propose a three-year action plan to upgrade quality systems, focusing on prominent issues and weak links in the operation of enterprises' manufacturing quality management systems. Through coordinated planning, comprehensive measures, and targeted support, the initiative aims to fully enhance system operating efficiency and elevate the overall quality management level of the industry, thereby providing strong momentum for the high-quality development of the cosmetics industry.

2. Continuously optimizing regulatory mechanisms and approaches. In response to new needs, new business models, and new trends in industrial development, the *Opinions* further optimize cosmetics regulatory mechanisms and approaches and continuously enhance the level and capacity of scientific regulation. The *Opinions* propose improving the quality and efficiency of regulation of online cosmetics distribution, adhering to the principles of "governing the internet via the internet", risk-based governance, and regulatory collaboration; strengthening focused monitoring of typical and serious online violations; continuously strengthening cooperation mechanisms with third-party platforms; and promoting coordinated action between administrative regulation and platform governance. The *Opinions* propose exploring optimized systems for cosmetics manufacturing management, encouraging provincial drug regulatory authorities to explore requirements for product release from off-site warehouses operating under the same manufacturing quality management system as the manufacturing site, and quality management requirements that adapt to intelligent cosmetics manufacturing. The *Opinions* propose improving the cosmetics adverse reaction monitoring and evaluation system, upgrading the national adverse reaction monitoring platform, promoting the sharing of national adverse reaction monitoring data, further strengthening in-depth analysis, scientific evaluation, and risk assessment of monitoring data, and advancing the adoption and application of monitoring and evaluation results.

3. Advancing graded and classified regulation of enterprises. Based on the characteristics of the cosmetics industry and regulatory patterns, the *Opinions* focus on optimizing regulatory strategies and exploring graded and classified regulation of cosmetics enterprises to allocate regulatory resources more rationally and

老机理等前沿基础研究，为技术创新提供科学支撑。同时，支持适合老年群体特点和需求的化妆品开发，在确保安全与功效的前提下加速其注册备案与上市进程。这一政策导向与国家银发经济战略同频共振，不仅体现了对老年群体美丽需求的重视和关怀，也为化妆品产业开辟了新的增长空间。随着"银发经济"潜力持续释放，专门针对老年群体研发的化妆品有望成为产业创新发展的重要赛道，培育出一批具有中国特色的银发化妆品品牌，实现社会效益与经济效益的双赢。

为适应化妆品产业智能化、绿色化发展需求，《意见》明确提出要加快实施化妆品电子标签。国家药监局拟于2026年2月起在部分省（市）开展电子标签试点工作。化妆品电子标签的应用将丰富标签信息的展示形式，消费者扫码即可"读懂"手中的产品，通过页面缩放、音频等功能，更清晰、生动地展示产品标签信息，有效增加标签的识读性和阅读便利性，满足适老化和不同人群需求，增强人民群众的消费体验和获得感。电子标签的应用还可简化实物标签标注内容，产品包装更加简洁美观。企业可通过信息系统更新电子标签内容，实现了标签信息的精细化、动态化管理，有效解决了重新印制标签的资源浪费问题，实现节能减负、降本增效。

此外，适应公众个性化、精准化消费需求，《意见》提出创新个性化服务方式。国家药监局已启动第二阶段化妆品个性化服务试点工作。

五、在"保安全、守底线"方面有哪些新举措

一是全面提升企业质量管理水平。化妆品生产质量管理体系的有效运行是保障企业质量管理水平的核心。《意见》精准定位提升化妆品企业质量管理水平这把"金钥匙"，提出利用3年时间，集中开展体系提升行动，聚焦企业生产质量管理体系运行中的突出问题和薄弱环节，通过统筹谋划、综合施策、帮扶引导等措施，全面优化体系运行效能，整体提升行业质量管理水平，为化妆品产业高质量发展注入强劲动能。

二是持续优化监管机制和监管手段。面对产业发展的新需求、新业态、新趋势，《意见》持续优化化妆品监管机制和监管手段，不断提升科学监管水平和监管能力。《意见》提出要提升化妆品网络经营监管质效，坚持"以网管网"、风险治理和监管协作，对典型、严重的网络违法行为加强重点监测，持续强化与第三方平台的协作机制，推动行政监管和平台

improve regulatory efficiency. Local drug regulatory authorities at all levels are encouraged to scientifically assess risk grades according to key factors such as enterprises' quality management systems and risk prevention and control capabilities. They are encouraged to explore the establishment of graded and classified regulatory systems, apply differentiated and targeted regulatory measures, and allocate more regulatory resources to high-risk areas and high-risk enterprises. These efforts will help significantly enhance regulatory efficiency and provide stronger safeguards for cosmetics quality and safety.

VI. Planning for the Development of the Cosmetics Standards System

Standards form the foundation for ensuring the quality and safety of cosmetics, regulating market order, and fostering innovative industrial development. In recent years, the NMPA has strengthened the development of the cosmetics standards system, established the NMPA Cosmetics Standardization Technical Committee, issued more than 170 cosmetics-related standards, and initiated the formulation and revision of six mandatory national standards, including the *Hygienic Standard for Cosmetics*.

The Opinions provide a more systematic plan for the cosmetics standards system and aim to build a more scientific, unified, authoritative, and efficient system of standards.

1. Improving the standards system. Accelerate the development of medium- and long-term plans for cosmetics standards; strengthen the baseline, binding role of mandatory national standards; and continuously advance the formulation and revision of standards in key areas such as general fundamentals, product safety, and testing methods, thereby enhancing the systematic, coordinated, and applicable nature of the standards system.

2. Addressing gaps in key areas of standards. Focusing on key areas and weak links such as ingredient safety control, safety and efficacy evaluation, and the application of emerging technologies, the *Opinions* call for a targeted plan of standards development projects to address issues of absent or outdated standards, thereby providing standards-based guidance for improving cosmetics quality and advancing technological innovation

3. Deepening alignment and cooperation with international standards. Strengthen tracking research and adoption/application of international cosmetics standards and promote the alignment of domestic standards with internationally advanced levels. At the same time, strive to take an active role in international standards development, enhance China's contribution and influence in global cosmetics standards governance, and support the internationalization of China's cosmetics industry.

VII. How to Enhance the Internationalization of Cosmetics Regulation

Cosmetics are globally circulating commodities. Promoting convergence, coordination, and mutual trust in international cosmetics regulation and advancing the reduction and exemption of animal testing will help lower technical barriers, facilitate the international trade of cosmetics, support Chinese cosmetics in expanding globally, and enable domestic consumers to access high-quality overseas products more easily and conveniently. In recent years, the NMPA has adhered to a high-level openness strategy and has continuously engaged in international exchanges and cooperation. Through multilateral and bilateral cooperation mechanisms, it has deepened regulatory and technical collaboration in the cosmetics industry and actively participated in the activities of the International Cooperation on Cosmetics Regulation (ICCR). The NMPA has also communicated China's industrial development progress, regulatory achievements, and regulatory philosophy, demonstrating China's commitment and responsibility in global cosmetics regulation.

To promote international trade in cosmetics and support high-quality Chinese cosmetics in expanding globally, the *Opinions* propose actively advancing the reduction and

治理协同发力。《意见》提出探索优化化妆品生产管理制度，鼓励省级药品监管部门探索与生产场地执行同一生产质量管理体系外设仓库的产品放行管理要求和适应化妆品智能化生产的质量管理要求。《意见》提出要完善化妆品不良反应监测与评价体系，优化升级国家不良反应监测平台，推动国家不良反应监测数据共享，进一步强化监测数据的深度分析、科学评价与风险研判，推动监测评价结果的转化运用。

三是推进企业分级分类监管。基于化妆品产业特点和监管规律，《意见》着力优化监管策略，探索推进化妆品企业分级分类监管，合理配置监管资源，提升监管效能。鼓励地方各级药品监管部门按照风险管理的原则，依据化妆品企业的质量管理体系、风险防控能力等关键要素，科学评估风险等级，探索建立企业分级分类监管制度，对企业实施差异化、精准化监管措施，将监管资源更多地集中于高风险领域和高风险企业，实现监管效能的全面提升，为化妆品质量安全提供更加坚实的保障。

六、化妆品标准体系建设如何规划

标准是保障化妆品质量安全、规范市场秩序、促进产业创新发展的基石。近年来，国家药监局加强化妆品标准体系建设，组建了国家药监局化妆品标准化技术委员会，发布各类化妆品标准170余项，启动《化妆品卫生标准》等6项强制性国家标准的制修订工作。

《意见》对化妆品标准体系进一步系统规划，致力于构建更加科学、统一、权威、高效的标准体系。

一是健全标准体系。加快研究制定化妆品标准建设中长期规划，强化强制性国家标准的底线约束作用，持续推进基础通用、产品安全、检测方法等关键领域标准的制修订工作，增强标准的系统性、协调性与适用性。

二是填补重点领域标准空白。聚焦原料安全控制、安全与功效评价、新兴技术应用等重点领域和薄弱环节，精准布局标准研制项目，解决标准缺失、滞后问题，为化妆品质量提升与技术创新提供标准化引领。

三是深化国际标准对接与合作。加强对国际化妆品标准体系的跟踪研究与转化应用，推动国内标准与国际先进水平接轨。同时，积极争取参与国际标准制定，增强我国在全球化妆品标准治理中的贡献度与话语权，助力中国化妆品走向世界。

七、如何提升监管国际化水平

化妆品是全球大流通商品。推动国际化妆

exemption of animal testing requirements. **1. Strengthen research and innovation in cosmetics safety assessment technologies** to enhance the scientific rigor, precision, and applicability of safety assessments. On this basis, promote reduced reliance on animal testing for cosmetics. Priority will be given to reducing or waiving animal testing requirements for products such as perming products, non-oxidative hair dyes, and cosmetics that use new ingredients during their monitoring period, with such exemptions to be gradually expanded to additional product categories. **2. Strengthen the top-level design for validating alternative methods to animal testing.** Adhering to integrated planning and coordinated implementation, and following the principle of "adopting alternatives wherever feasible," accelerates the development, adoption, and application of alternative test methods. **3. Leverage the role of cosmetics regulatory science innovation bases.** Focusing on industry expectations and regulatory needs, strengthen fundamental, cutting-edge, and innovative research on alternative methods to animal testing, and comprehensively enhance China's capabilities in cosmetics safety assessment and scientific regulation.

VIII. Specific Measures to Enhance Governance Capacity

To meet the new situation and new requirements brought by the innovative development of the cosmetics industry, the *Opinions* deploy reform measures in three aspects around modernization of regulatory capacity and improvement of review and approval efficiency, aiming to build a scientific, efficient, and standardized modern governance system for cosmetics.

1. Deepening reform of registration and filing. The *Opinions* outline a series of specific measures to optimize registration and filing management. Application dossiers will be simplified. While ensuring product quality and safety and meeting regulatory needs, products under the same brand with similar formulations may share safety assessment and efficacy evaluation documentation. For products that require re-registration or re-filing due to a change in manufacturing site, part of the original technical documentation may be reused. Except for efficacy claims such as spot corrector and whitening, sunscreen, and preventing hair loss, enterprises may independently select appropriate efficacy evaluation methods. Ingredient safety information will be kept on file by enterprises for inspection, substantially reducing their submission burden. The review mechanism will be further optimized by establishing a coordinated national–provincial review system for special cosmetics and promoting the integrated use of review resources. Registration changes will be subject to categorized management: for high-risk changes, the review period will be shortened from 90 to 60 working days; for low-risk changes, to 45 working days. For changes that do not involve safety or efficacy claims, enterprises will be permitted to maintain product information on their own, thereby significantly improving approval efficiency.

2. Strengthening regulatory teams and capacity building. In view of the rapid development of the cosmetics industry and accelerated product iteration, the capabilities of current regulatory teams still need to be further strengthened. The *Opinions* explicitly call for strengthening professional technical capacity in cosmetics review, optimizing the structure of cosmetics inspector teams, and enhancing systematic training, professional management, and scientific performance evaluation for review and inspection personnel, thereby comprehensively improving the professional capability and execution efficiency of regulatory teams. In terms of optimizing mechanisms, provincial drug regulatory authorities are encouraged to strengthen exchanges and cooperation, enhance resource sharing, information interconnection, and regulatory collaboration, actively explore innovative regulatory models, and establish a modern regulatory system characterized by efficient coordination and integrated operation.

3. Strengthening regulatory science research

品监管趋同、协调和信赖，推行动物试验减免，将有效减少技术壁垒，畅通化妆品国际贸易，在支持我国化妆品扬帆出海的同时，也将有利于国内消费者轻松便捷购买国外优质产品。近年来，国家药监局坚持高水平开放战略，持续开展国际交流合作，通过多边、双边合作机制，深化化妆品监管和技术交流，积极参与国际化妆品监管联盟（ICCR）活动，宣传我国产业发展状况、监管成效及管理理念，在全球化妆品监管中展现中国担当。

为促进化妆品国际贸易，支持我国优质化妆品出海，《意见》提出积极推进动物试验减免。**一是加强化妆品安全评估技术研究与创新**，提升评估工作的科学性、精准性和应用性，在此基础上，推动减少化妆品动物试验依赖，优先从烫发、非氧化性染发和使用了监测期新原料的化妆品着手，减免动物试验要求，并逐步扩大到其他品类。**二是强化动物替代方法验证工作顶层设计**，坚持统筹规划、整体推进，按照"能转尽转"的原则，加速动物替代试验方法开发、转化和应用。**三是发挥化妆品监管科学创新研究基地作用**，围绕行业所盼、监管所需，加强动物替代试验方法的基础性、前沿性、创新性研究，全面提升我国化妆品安全评估能力和科学监管水平。

八、提升治理能力有哪些具体措施

为适应化妆品产业创新发展的新形势与新要求，《意见》围绕监管能力现代化与审评审批效率提升，系统部署了三个方面改革举措，着力构建科学、高效、规范的现代化化妆品治理体系。

一是深化注册备案改革。《意见》推出一系列优化注册备案管理的具体措施。简化申报资料，在保障质量安全与监管需要的前提下，允许配方近似的同一品牌产品共用安全评估及功效评价资料；对因产地变更需重新注册备案的产品，允许沿用部分原技术资料；除祛斑美白、防晒、防脱发等功效外，企业可自主选择功效评价方法；原料安全信息改为企业自行存档，切实减轻企业申报负担。优化审评机制，建立特殊化妆品国家与省级协同审评机制，推进审评资源整合；对注册变更事项实施分类管理，将高风险事项审评时限由90个工作日压缩至60个工作日，低风险事项压缩至45个工作日，对不涉及安全性与功效宣称的变更，允许企业自行维护产品信息，显著提升审批效率。

二是强化监管队伍与能力建设。面对化

and the development of intelligent regulation. The *Opinions* specify the full utilization of regulatory science innovation research bases to focus major research projects on key areas such as safety assessment, innovative products and ingredients, and risk early warning, while accelerating the development of new regulatory tools, standards, and methodologies. At the same time, the digital transformation of regulation will be accelerated, promoting the online processing of all aspects and the entire process of cosmetics regulation. This includes upgrading the cosmetics regulation APP and actively exploring the application of artificial intelligence technologies in filing, manufacturing, and distribution regulation, thereby enhancing the overall intelligence of the regulation.

(November 17, 2025)

妆品产业快速发展与产品迭代加速的新形势，当前监管队伍的能力仍需进一步加强。《意见》明确提出，要充实化妆品审评专业技术力量，优化化妆品检查员队伍结构，强化化妆品审评和检查员队伍的系统化培训、专业化管理与科学化考核，全面提升监管队伍的专业能力与执行效能。在机制优化方面，鼓励省级药品监管部门之间深化交流协作，加强资源共享、信息互通与监管协同，积极探索监管模式创新，构建协同高效、联动一体的现代化监管体系。

三是加强监管科学研究与智慧监管建设。《意见》明确要充分发挥监管科学创新研究基地作用，围绕安全评估、创新产品与原料、风险预警等关键领域布局重大科研项目，加快研发监管新工具、新标准、新方法。同时加快推进监管数字化转型，推动化妆品监管全业务全流程在线办理，优化升级化妆品监管APP功能，积极探索人工智能技术在备案、生产和经营监管等环节的应用，全面提升监管的智能化水平。

(2025-11-17)

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.
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