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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Revision and Release of the *Good Manufacturing Practice for Medical Devices*

On November 4, the National Medical Products Administration (NMPA) released the revised version of the *Good Manufacturing Practice for Medical Devices* (hereinafter referred to as the GMP). The new GMP for medical devices shall come into effect as of November 1, 2026.

The new GMP is revised on the basis of the previous version released in 2014. It is an important measure by the NMPA to implement the *"Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Regulation to Promote the High-Quality Development of the Pharmaceutical Industry ([2024] No. 53)"* and relevant laws and regulations, comprehensively strengthen the quality management system construction of medical device enterprises, and promote the overall improvement of quality management capacity in China's medical device industry.

The new GMP systematically integrates the latest concepts of risk management throughout the whole life cycle of medical devices and new requirements for quality management system construction both domestically and internationally in recent years. While meeting the new demands for innovation and high-quality development of the industry, it also incorporates new regulatory requirements in the digital intelligence era. The aim is to comprehensively promote high-quality industrial development through the institutionalization and legalization of new regulation rules, making it an upgraded version of the GMP that promotes comprehensive progress in enterprises' QMS in the new era.

The revised GMP consists of 15 chapters and 132 articles, adding three new chapters on quality assurance, validation and verification, and contract manufacture and outsourcing. Other chapters and articles have also been amended more or less. The new GMP has the following characteristics: First, it further strengthens the concept of quality risk management, ensuring that risk management runs consistently from R&D design to after-sales service. Second, it further strengthens the construction of the quality assurance system within the quality management system, ensuring the continuous stability of large-scale manufacturing processes. Third, it further strengthens management requirements for new business models such as contract manufacture, clarifying responsibilities at each stage to ensure high-level safety across the entire chain. Fourth, it further emphasizes the importance of the key link of "validation and verification" in operation specification and improving output reliability, ensuring effective control of key elements in the product manufacturing process. Fifth, it further encourages the digital-intelligent transformation in manufacturing, ensuring the effective application of artificial intelligence, information technology, and the Unique Device Identification system.

The implementation of the new GMP will further lay a solid institutional foundation for ensuring the safety and effectiveness of medical devices for the Chinese public and promoting the normative and orderly development of the medical device industry.

(2025-11-04)

头条

《医疗器械生产质量管理规范》修订发布

11月4日，国家药监局发布新版《医疗器械生产质量管理规范》（以下简称《规范》）。新版《规范》将于2026年11月1日起施行。

新版《规范》是在2014年发布的《规范》基础上的修订版，是国家药监局贯彻落实《国务院办公厅关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》（国办发〔2024〕53号）以及相关法规规章规定，全面加强医疗器械企业质量管理体系建设，推动我国医疗器械行业质量管理水平整体提升的重要举措。

新版《规范》系统融合了近年来国内外医疗器械全生命周期质量风险管理新理念和质量管理体系建设新要求，在契合产业创新高质量发展新需求的同时，融合了数智化时代监管新要求，以期通过新管理规则的制度化、法制化，全面促进产业高质量发展，是新时代新阶段促进企业质量管理体系全面进步的《规范》升级版。

修订后的《规范》共15章132条，增加了质量保证、验证与确认、委托生产与外协加工三个章节，其他章节条款也进行了不同程度的修改。新版《规范》体现以下特点：一是进一步强化质量风险管理理念，确保从研发设计到售后服务风险管理一以贯之；二是进一步强化质量管理体系中质量保证系统建设，确保规模化生产制造过程的持续稳定；三是进一步强化委托生产等新业态管理要求，明晰各环节责任，确保全链条高水平安全；四是进一步强化“验证与确认”这一关键环节在操作规范和提升结果可靠性方面的重要价值，确保产品生产过程关键要素得到有效控制；五是进一步强化鼓励生产制造数智化转型，确保人工智能、信息技术和医疗器械唯一标识的有效应用。

新版《规范》的实施，将为保障我国公众用械安全有效，促进医疗器械行业规范有序发展进一步奠定坚实的制度基础。

（2025-11-04）

Published by
China Center for Food and Drug International Exchange

Drugs

Announcement of the National Medical Products *Administration on Issuing the Administrative Provisions on Inspection and Export Certificate for Pharmaceutical Products Exported by Pharmaceutical Manufacturers([2025] No. 113)*

In order to support the export trade of pharmaceutical products and strengthen the management of inspection and export certificate for exported pharmaceutical products of pharmaceutical manufacturers, the National Medical Products *Administration has formulated the Administrative Provisions on Inspection and Export Certificate for Pharmaceutical Products Exported by Pharmaceutical Manufacturers*, which is hereby promulgated and shall come into force as of January 1, 2026.

It is hereby announced.

National Medical Products Administration

November 17, 2025

(2025-11-21)

药品

国家药监局关于发布药品生产企业出口药品检查和出口证明管理规定的公告（2025年第113号）

为支持药品出口贸易，加强药品生产企业出口药品检查和出口证明的管理，国家药监局制定了《药品生产企业出口药品检查和出口证明管理规定》，现予发布，自2026年1月1日起施行。

特此公告。

国家药监局

2025年11月17日

（2025-11-21）

Policy Interpretation of the National Medical Products Administration on Issuing the *Administrative Provisions on Inspection and Export Certificate for Pharmaceutical Products Exported by Pharmaceutical Manufacturers*

I. Background for Development

In order to implement the spirit of "Supporting the Export Trade of Drugs and Medical Devices" outlined in the *Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of the Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry* (GBF [2024] No. 53), the National Medical Products Administration (NMPA) has formulated the *Administrative Provisions on Inspection and Export Certificate for Pharmaceutical Products Exported by Pharmaceutical Manufacturers*, (hereinafter referred to as the "Provisions"). These Provisions stipulate that inspections of exported pharmaceutical products will be conducted in accordance with *Good Manufacturing Practice* (GMP), and export certificates and other relevant services will be provided for Chinese pharmaceutical products to support and encourage the entry of more Chinese pharmaceutical products into the international market.

II. Scope of Application

The term "exported pharmaceutical product" in the Provisions refers to the product manufactured by manufacturers within the territory of China that hold a *Drug Manufacturing License*, exported to other countries (regions), and regulated as pharmaceutical products and marketed in the importing countries (regions), including the products that have been marketed and those not yet marketed within the territory of China. The scope of "marketing" in the Provisions includes the products for which a marketing application is proposed, in addition to the products that have been marketed in the importing countries (regions). In terms of product category, it includes pharmaceutical preparations, active substances, and traditional Chinese medicine dispensing granules. Additionally, an export certificate can be applied for intermediate products of pharmaceutical preparations with reference to the Provisions.

The Provisions require that the production activities of exported pharmaceutical products

《药品生产企业出口药品检查和出口证明管理规定》政策解读

一、制定背景

为落实《国务院办公厅关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》（国办发〔2024〕53号）关于“支持药品医疗器械出口贸易”的精神，国家药品监督管理局制定《药品生产企业出口药品检查和出口证明管理规定》（以下称《规定》），按照药品生产质量管理规范（GMP）对出口药品实施检查，同时为我国药品提供出口证明等服务事项，支持和鼓励更多中国药品进入国际市场。

二、适用范围

《规定》所称出口药品，是指中国境内持有《药品生产许可证》的企业生产，出口至其他国（地区）并在进口国（地区）按照药品管理且上市销售的产品，包括在中国境内已上市产品和未上市产品。《规定》条文中的“上市销售”所指范围，除在进口国（地区）已上市销售的产品外，也包括拟申请上市销售的产品。在产品类别上，包括药品制剂、原料药、中药配方颗粒等；另外，药品制剂中间产品可参照本规定申请出具出口证明。

《规定》要求出口药品的生产活动在《药

shall be conducted in strict compliance with the GMP in the production workshops and production lines specified in the *Drug Manufacturing License*. Where the manufacturers of exported pharmaceutical products produce chemical products and other non-pharmaceutical products at the same time, these products shall not be exported under the name of pharmaceutical products, even if they possess pharmaceutical activity. Furthermore, the documents, such as the *Drug Manufacturing License* issued by the drug regulatory authorities, shall not be used in the trade of such products.

III. Measures to Facilitate the Export of Pharmaceutical Products

Firstly, the scope of the export certificate is expanded. For the exported pharmaceutical products manufactured in accordance with GMP by pharmaceutical manufacturers, an export certificate can be applied, regardless of whether the products have been approved for marketing in China or not.

Secondly, the validity period of the export certificate is standardized. The validity period of the *Certificate of a Pharmaceutical Product* is adjusted from 2 years to 3 years, which is consistent with the *Written Confirmation for Active Substances Exported to the European Union (EU)*. Provincial drug regulatory authorities shall provide services during the handling of the application for export certificates to ensure that the application for certificate renewal before the expiry date is handled in an orderly manner, thus avoiding the "gap period", where the old certificate has expired but the new certificate has not yet been issued. If the regulatory authorities in importing countries (regions) consider that the existing certificates have been issued earlier (e.g., more than 18 months) and expect the manufacturers to provide a new certificate, the manufacturers may apply for a new certificate, and the provincial drug regulatory authorities shall handle the application according to the procedures.

Thirdly, the time limit for issuing certificates is specified. The Provisions clearly require that the time limit for handling the application for an export certificate in the work rules set by each provincial drug regulatory authority shall not exceed 20 working days. However, the time required for technical review, evaluation, on-site inspection by the drug regulatory authorities, and any time needed for manufacturer rectification shall not be counted into the time limit.

Fourthly, an export certificate can be applied for intermediate products of pharmaceutical preparations. When intermediate products of pharmaceutical preparations (including drug substances of biological products) manufactured by pharmaceutical manufacturers have been exported and used for the production of pharmaceutical preparations in the importing countries (regions), if the regulatory authorities in the importing countries (regions) require an export certificate for these intermediate products of pharmaceutical preparations, an export certificate can be applied according to the types of products that have not been marketed within the territory of China. For pharmaceutical manufacturers producing and exporting pharmaceutical intermediate products, if their Drug Manufacturing License does not include this intermediate product in its production scope, they should ensure that the manufacturing scope includes the relevant pharmaceutical preparation. There is no need to apply for an extension of the production scope to include the intermediate product specifically.

Fifthly, the template of the *Certificate of a Pharmaceutical Product* is updated. The template of *Certificate of a Pharmaceutical Product* adopts the latest format recommended by the World Health Organization (WHO), issued in 2021, to align with the WHO Certification Scheme on the Quality of

品生产许可证》载明的生产车间、生产线上严格按照药品GMP开展。出口药品生产企业如同时生产化工产品等非药用产品的，即使该产品具有药物活性，也不得以药品名义出口，在该产品的贸易中不得使用《药品生产许可证》等由药品监督管理部门发放的文件。

三、为药品出口提供便利的举措

一是拓宽出口证明出证范围。对于药品生产企业按照药品GMP生产的出口药品，无论是否在中国批准上市，均可以申请出具出口证明。

二是统筹出口证明的有效期。《药品出口销售证明》有效期由2年调整为3年，与《出口欧盟原料药证明文件》一致。省级药品监督管理部门应当在出口证明的办理过程中做好服务，确保在有效期届满前后的新旧证明衔接有序，避免出现旧证明有效期已届满、而新证明尚未出具的“空窗期”。如进口国（地区）认为已有的证明出具时间较早（比如超过18个月）、希望企业提供新证明的，企业可以申请新证明，省级药品监督管理部门应当按程序予以办理。

三是限定证明出具时限。《规定》明确要求各省级药品监督管理部门设定的工作细则中，出口证明的办理时限最长不超过20个工作日，但药品监督管理部门开展技术审查和评定、现场检查以及企业整改等所需时间不计入时限。

四是药品制剂中间产品可以申请出具出口证明。药品生产企业生产的药品制剂中间产品（包括生物制品原液等）出口后在进口国（地区）用于药品制剂生产，如进口国（地区）要求对药品制剂中间产品提供出口证明的，可按照未在境内上市产品类型申请出口证明。生产并出口药品制剂中间产品的药品生产企业，《药品生产许可证》生产范围未包含该药品制剂中间产品的，应当具备该药品制剂的生产范围，无需专门办理增加该药品制剂中间产品的生产范围。

五是更新《药品出口销售证明》模板。《药品出口销售证明》模板采用世界卫生组织（WHO）在2021年发布的最新推荐格式，以更好契合WHO国际贸易药品认证计划。《药品出口销售证明》申请者应当细致了解模板格式的变化情况和最新填报要求。

Pharmaceutical Products Moving in International Commerce. Applicants for the *Certificate of a Pharmaceutical Product* shall carefully understand the changes in the template format and the latest requirements for filling and application.

IV. Measures to Ensure the Production Compliance of Exported Pharmaceutical Products

To comply with WHO's assessment requirements for National Regulatory Authorities (NRAs) and to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the Provisions specify the compliance and inspection requirements for the production of exported pharmaceutical products. The relevant measures include:

Firstly, pharmaceutical manufacturers are guided to establish dossiers for exported pharmaceutical products, with inspections based on the information in such dossiers. The exported pharmaceutical product dossiers serve as the information foundation for the production management of exported pharmaceutical products by the manufacturers, as well as a key tool for regulatory inspection of exported pharmaceutical products.

Secondly, targeted inspections can be conducted based on the export certificate. The export certificate contains proof information such as GMP compliance for specific products or dosage forms, and the inspection period. For pharmaceutical products that have obtained export certificates, on the basis of regulating the overall compliance of manufacturers, the provincial drug regulatory authorities may conduct more targeted inspections in combination with the export certificate information.

Thirdly, an extended inspection may be conducted, when necessary, for storage and transportation companies of exported pharmaceutical products within the territory of China. The Provisions require that entities involved in exporting pharmaceutical products, such as manufacturers of exported pharmaceutical products or entrusting parties entrusting the manufacturing of exported pharmaceutical products, shall ensure that storage and transportation companies of the exported pharmaceutical products are subject to audits and extended inspections by the drug regulatory authorities through the letter of commitment, storage and transportation agreements, etc. This measure helps ensure the quality of exported pharmaceutical products and the rights and interests of overseas patients in medication safety.

V. Description for the Information Related to the Exported Pharmaceutical Products in the *Drug Manufacturing License*

After the implementation of the Provisions, when applying for the issuance, change, or renewal of the *Drug Manufacturing License,* where the applicants have the designated production scopes, production workshops, and production lines for exported pharmaceutical products, they shall apply for GMP compliance inspection of exported pharmaceutical products at the same time. Manufacturers can submit the application at their own time, which shall be no later than the time point at which they apply for changes to license items related to pharmaceutical products marketed domestically for the first time after the implementation of the Provisions. Where no change occurs to license items after the implementation of the Provisions and before the manufacturers apply for renewal of the *Drug Manufacturing License*, they can apply together at the time of renewal of the license. Where a manufacturer applies for an export certificate, the manufacturing site, production scope, production workshop, and production line of the relevant exported pharmaceutical products shall first be specified in the *Drug Manufacturing License*.

With reference to the *Provisions for the Supervision and Administration of Drug Manufacturing* and *Announcement of the*

四、保障出口药品生产合规的举措

为符合WHO对国家监管体系（NRA）评估要求，同时为加入药品检查合作计划（PIC/S），《规定》明确出口药品生产合规要求和检查要求。相关举措包括：

一是指导企业建立出口药品档案，结合档案信息开展检查。出口药品档案是企业做好出口药品生产管理的信息基础，也是出口药品监督检查的重要抓手。

二是结合出口证明，实施针对性检查。出口证明载有具体品种或者剂型的药品GMP符合性、检查周期等证明事项。对于获得出口证明的药品，省级药品监督管理部门在督促企业整体合规的基础上，可以结合出口证明信息，实施更有针对性的检查。

三是对出口药品在中国境内的储存运输企业必要时可以开展延伸检查。《规定》要求出口药品生产企业或者委托生产出口药品的委托方等出口药品的主体应当通过承诺书、储存运输协议等方式，确保从事出口药品储存运输的企业接受审核和药品监督管理部门的延伸检查。这有利于保障出口药品质量和境外患者安全用药的权益。

五、《药品生产许可证》中出口药品相关信息的说明

本规定施行后，申请《药品生产许可证》核发、变更或者重新发证时，申请者有专门用于出口药品的生产范围、生产车间、生产线的，应当同时申请出口药品GMP符合性检查。企业可自行选择时间提出申请，但应当不迟于本规定施行后企业首次办理境内上市药品相关许可事项变更的时间节点；本规定施行后至企业申请重新发放《药品生产许可证》前未发生许可事项变更的，可在重新发证时一并提出申请。企业申请出具出口证明的，《药品生产许可证》应当先载明相关出口药品的生产地址、生产范围、生产车间、生产线。

省级药品监督管理部门参照《药品生产监督管理办法》和《国家药监局关于实施新修订〈药品生产监督管理办法〉有关事项的公告》（2020年第47号），对药品生产企业的生产条件进行审查，开展药品GMP符合性检查，符合

National Medical Products Administration on the Issues Pertaining to Implementation of the Newly Revised Provisions for the Supervision and Administration of Drug Manufacturing ([2020] No. 47), the provincial drug regulatory authorities shall review the production conditions of pharmaceutical manufacturers, conduct GMP compliance inspections, and, for those complying with GMP, specify the relevant manufacturing site, production scope, production workshop, production line and other information of exported pharmaceutical products in the *Drug Manufacturing License.*

VI. Description for Filling and Application Related to the Exported Pharmaceutical Product Dossiers

The information of the exported pharmaceutical product dossiers filled in by manufacturers in the information system of drug regulatory authorities is not part of the content that requires approval or filing by the drug regulatory authorities.

The materials to be kept by manufacturers themselves, namely, those under Items (14) and (15) of Article 14 of the Provisions, shall always be included in accordance with the requirements for each item of the exported pharmaceutical product dossiers.

The exported pharmaceutical product dossiers shall accurately reflect the status of manufacturing and sales of the exported pharmaceutical products of the manufacturers. Where a manufacturer establishes and updates the exported pharmaceutical product dossiers (including changes to the dossier information), it shall complete this within the relevant time limit specified in Article 16 of the Provisions.

The entities responsible for establishing exported pharmaceutical product dossiers shall establish the relevant exported pharmaceutical product dossiers after starting a new business of exported pharmaceutical products. "New business of exported pharmaceutical products" includes: obtaining the marketing authorization certificates from the importing countries (regions) for the products held by the exported pharmaceutical product manufacturers, signing an agreement for contract manufacturing (for the production of pharmaceutical products marketed in the importing countries or regions), etc. Before the implementation of the Provisions, where the business of exported pharmaceutical products has been terminated, there is no need to establish relevant exported pharmaceutical product dossiers.

The entities responsible for establishing exported pharmaceutical product dossiers shall strengthen the management of changes to dossier information. For example, if products for which shared facilities are used for production are added, the risk assessment of production in shared facilities shall be re-conducted, and a new assessment report shall be formed; where the legal representative is changed, the legal representative after the change shall re-sign the compliance statement of exported pharmaceutical products.

Where the same pharmaceutical product is exported to multiple countries (regions), and the relevant information (such as the generic name, trade name, specification, label, and package insert) is inconsistent among the importing countries (regions), the relevant information of the pharmaceutical product in each importing country (region) shall be filled in under the relevant items of the exported pharmaceutical product dossier.

The Provisions require that the information on the annual manufacturing and sales volume of exported pharmaceutical products in the previous natural year shall be filled in before April 30 of each year. The annual manufacturing and sales volume in 2025 shall be filled in by April 30, 2026.

For exported pharmaceutical products purchased by international organizations but have not obtained marketing authorization from the importing countries (regions), relevant documents that meet the procurement requirements of the international organizations

药品GMP的，在《药品生产许可证》载明出口药品相关的生产地址、生产范围、生产车间、生产线等信息。

六、出口药品档案有关填报说明

企业在药品监督管理部门建设的信息系统中填报的出口药品档案信息，不属于经药品监督管理部门审批、备案的内容。

针对出口药品档案的各项要求，始终包含企业自行保存的材料，即《规定》第十四条的第（十四）（十五）项。

出口药品档案应当准确反映企业出口药品生产销售情况。企业建立、更新出口药品档案（包括档案信息变更）的，应当在《规定》第十六条的有关时限内完成。

出口药品档案的建立者应当在新开展出口药品业务后建立相关出口药品档案。“新开展出口药品业务”包括：出口药品生产企业持有的品种获得进口国（地区）的上市许可证明、签署接受委托生产协议（生产进口国或者地区的上市药品）等。在《规定》施行前，出口药品业务已终止的，无需建立相关出口药品档案。

出口药品档案建立者应当加强档案信息变更管理，例如：增加共线生产品种的，应当重新开展共线生产风险评估并形成新的评估报告；法定代表人变更的，应当由变更后的法定代表人重新签署出口药品合规声明。

同一种药品出口至多个国（地区），相关信息（例如通用名、商品名、质量标准、标签、说明书等）在各进口国（地区）不一致的，应当在出口药品档案的相关项目下填报药品在所有进口国（地区）的相关信息。

《规定》要求每年4月30日前填报上一个自然年度的出口药品年度生产销售数量信息，2026年4月30日前应当填报2025年度生产销售数量。

出口药品属于国际组织采购，但未取得进口国（地区）上市许可的，出口药品档案的（三）（四）（七）（十四）项等涉及进口国（地区）的项目，应当提供或者保存符合国际组织采购要求的相关文件。

七、关于“与中国有相关协议的国际组织”的说明

shall be provided or retained under items involving the importing country (region), including Items (III), (IV), (VII) and (XIV) of the exported pharmaceutical product dossiers.

VII. Description for "International Organizations That Have Signed Relevant Agreements with Chinese Regulatory Authorities"

"International organizations that have signed relevant agreements with Chinese regulatory authorities" currently refer to the WHO and the Medicines Patent Pool (MPP). In order to serve manufacturers and save regulatory resources, for pharmaceutical products that have not been marketed within the territory of China and have obtained WHO pre-certification or MPP authorization for production, the provincial drug regulatory authorities may specify the manufacturing site, production scope, production workshop and production line of the relevant exported pharmaceutical products in the *Drug Manufacturing License* according to the application of manufacturers, and exempt on-site inspection for the relevant products during the process of handling the application for the *Certificate of a Pharmaceutical Product.*

It should be noted that, where the manufacturing site, production scope, production workshop and production line that are exclusively used for the exported pharmaceutical products are intended to be used subsequently for production of pharmaceutical products to be marketed within the territory of China, the manufacturers of exported pharmaceutical products shall apply for the changes to *Drug Manufacturing License* in accordance with the relevant requirements for pharmaceutical products to be marketed within the territory of China.

VIII. Description for Exemption from Inspection during the Process of Handling the Application for *Written Confirmation for Active Substances Exported to the European Union (EU)*

Where the pharmaceutical manufacturer has passed the GMP inspection by the WHO, the European Directorate for the Quality of Medicines & Healthcare (EDQM) and the drug regulatory authorities of the EU member states, the provincial drug regulatory authorities may exempt it from on-site inspection during the process of handling the application for *Written Confirmation for Active Substances Exported to the European Union (EU)*, and indicate the authority that conducts the GMP inspection in the Written Confirmation.

IX. Description for "Information System Built by Drug Regulatory Authorities" in the Provisions

"Information system built by drug regulatory authorities" refers to the pharmaceutical product business application system of NMPA and the self-built systems of the provincial drug regulatory authorities. Among them, the pharmaceutical product business application system of NMPA is divided into categories of information collection, review, approval, and filing.

The pharmaceutical product business application system (information collection) is used to fill in the information and materials required in Items (1) to (13) of Article 14 of the Provisions. Users shall access the operation manual available on the "Help Document" for the specific operation process. As of December 1, 2025, the filling and application function of exported pharmaceutical product dossiers of this system will be available in all provinces nationwide.

The pharmaceutical product business application system (review, approval, and filing) is used to apply for an export certificate. After registering and completing real-name authentication in the NMPA government affairs service portal, the applicants may apply for an export certificate. Once the export certificate is obtained, it can be viewed or downloaded electronically in the "My License" section of the legal person space or on the "NMPA APP". It should be noted that the export certificate falls under a service item, not under a review, approval, and filing item. The

“与中国有相关协议的国际组织”，目前是指WHO和药品专利池组织（MPP）。为服务企业、节约监管资源，对于未在中国境内上市的药品，如获得WHO预认证或者MPP授权生产的，省级药品监督管理部门可以依企业申请在《药品生产许可证》中载明相关出口药品的生产地址、生产范围、生产车间、生产线，对相关品种在《药品出口销售证明》的办理过程中免于现场检查。

需要说明的是，如专门用于出口药品的生产地址、生产范围、生产车间、生产线后续拟用于中国境内上市药品生产，出口药品生产企业应当按照中国境内上市药品的有关要求办理《药品生产许可证》变更等手续。

八、关于《出口欧盟原料药证明文件》办理过程中免于检查情形的说明

如药品生产企业通过WHO、欧洲药品质量管理局（EDQM）、欧盟成员国药品监督管理机构的药品GMP检查，省级药品监督管理部门在该生产企业《出口欧盟原料药证明文件》办理过程中可以免于现场检查，在证明文件中写明实施药品GMP检查的机构。

九、《规定》中“药品监督管理部门建设的信息系统”的说明

“药品监督管理部门建设的信息系统”是指国家药品监督管理局药品业务应用系统和省级药品监督管理部门的自建系统。其中，国家药品监督管理局药品业务应用系统分为信息采集类和审批备案类。

药品业务应用系统（信息采集类）用于填报《规定》第十四条第（一）至（十三）项所要求的信息和材料。用户可在“帮助文档”中获取操作手册，了解具体操作流程。该系统于2025年12月1日起面向全国各省份开放出口药品档案填报功能。

药品业务应用系统（审批备案类）用于申请出口证明。申请者在国家药品监督管理局政务服务门户注册并实名认证后，可申请出具出口证明。获得出口证明后，可在法人空间“我的证照”栏目或者“中国药监APP”查看或者下载相应的电子证明。需要说明的是，出口证明属于服务事项，不属于审批、备案事项。《规

export certificate applications accepted before the implementation of the Provisions shall be handled in accordance with the original relevant provisions and templates.

Provincial drug regulatory authorities may, based on the work needs of their respective provinces, establish their own systems for filling in and submitting exported pharmaceutical product dossiers and handling applications for export certificates. The specific launch date and operation process of self-built systems shall be subject to the requirements of the corresponding provincial drug regulatory authorities. Before the launch of the self-built systems of provincial drug regulatory authorities, manufacturers shall use the pharmaceutical product business application system of the NMPA to fill in and submit exported pharmaceutical product dossiers and apply for export certificates within the specified time limit. After the self-built systems of provincial drug regulatory authorities are launched, they shall be connected to the NMPA system to exchange information on exported pharmaceutical product dossiers and export certificates.

X. Description for Application for *Certificate of a Pharmaceutical Product* in the Case of Cross-Provincial Contract Manufacturing

Where an exported pharmaceutical product has been marketed within the territory of China or an application for marketing authorization has been submitted, and cross-provincial contract manufacturing is involved, the entrusting party may choose one of the following two application methods based on its own needs: The first is to apply to the provincial drug regulatory authority in the place where the entrusting party is located, and the provincial drug regulatory authority in the place where the entrusting party is located shall issue the certificate based on the GMP compliance inspection results of the entrusted manufacturer in another province after inquiring; The second is that the entrusting party shall issue the *Statement of Entrusting for Application for Certificate of a Pharmaceutical Product* in accordance with the template attached to the Provisions, and the entrusted manufacturer shall apply to the provincial drug regulatory authority in the place where it is located to issue a certificate.

XI. Description of the Relevant Regulations for the Exportation and Undertaking Contract Manufacturing of Exported Narcotic Drugs, Psychotropic Substances, Preparations Containing Narcotic Drugs or Psychotropic Substances, Pharmaceutical Precursor Chemicals, Preparations Containing Pharmaceutical Precursor Chemicals, and Protein Anabolic Preparations and Peptide Hormones Listed in the Stimulant Catalog

According to the relevant requirements of the *Drug Administration Law*, export licenses shall be obtained for narcotics and psychotropic drugs to be exported. In accordance with the relevant requirements of the *Measures for the Administration of the Production of Narcotic Drugs and Psychotropic Substances (Interim)* (GSYJA [2005] No. 528), where the exported pharmaceutical product manufacturers undertake contract manufacturing of narcotic drugs, psychotropic substances, and preparations containing narcotic drugs or psychotropic substances entrusted by the overseas marketing authorization holders and applicants, approval from the NMPA shall be obtained. The pharmaceutical products that have been approved for production shall not be sold or used within the territory of China in any form, and shall be completely exported after obtaining an export license. According to the relevant requirements of the *Regulations on the Management of Precursor Chemicals*, export licenses issued by the commercial authorities shall be obtained for the export of pharmaceutical precursor chemicals. In accordance with the relevant requirements of the *Measures for the Administration of Pharmaceutical Precursor Chemicals* (Order

定》施行前受理的出口证明申请，按照原相关规定和相关模板办理。

省级药品监督管理部门可以根据本省工作需要，自建系统用于填报出口药品档案、办理出口证明。自建系统的具体上线时间和操作流程以相关省级药品监督管理部门要求为准。省级药品监督管理部门自建系统上线前，企业应当使用国家药品监督管理局药品业务应用系统按照规定时限填报出口药品档案、申请出口证明。省级药品监督管理部门自建系统上线后，与国家药品监督管理局系统对接，互通出口药品档案和出口证明信息。

十、跨省委托生产情形下申请药品出口销售证明的说明

出口药品已在中国境内上市或者已提交上市许可申请的，且涉及跨省委托生产的，委托方可以结合自身需求，选择以下两种申请方式：第一种是向委托方所在地省级药品监督管理部门申请，由委托方所在地省级药品监督管理部门跨省查询受托生产企业的药品GMP符合性检查情况后出具证明；第二种是委托方按照《规定》所附模板出具《委托办理药品出口销售证明的声明》，由受托生产企业向其所在地省级药品监督管理部门申请出具证明。

十一、出口和接受委托生产出口麻醉药品、精神药品、含麻醉药品或者含精神药品的制剂、药品类易制毒化学品、含药品类易制毒化学品的制剂以及兴奋剂目录所列蛋白同化制剂、肽类激素有关规定的说明

依据《药品管理法》有关要求，出口麻醉药品和精神药品，应当取得出口准许证。依据《麻醉药品和精神药品生产管理办法（试行）》（国食药监安〔2005〕528号）有关要求，出口药品生产企业接受境外药品上市许可的持有者、申请者委托生产麻醉药品、精神药品以及含麻醉药品或者含精神药品的制剂的，应当经国家药品监督管理局批准。经批准后生产的药品不得以任何形式在中国境内销售、使用，应当在办理出口准许证后全部出口。依据《易制毒化学品管理条例》有关要求，出口药品类易制毒化学品，应当取得商务部门核发的出口许可证。依据《药品类易制毒化学品管理办法》

No. 72 of the Ministry of Health), pharmaceutical manufacturers shall not undertake contract manufacturing of pharmaceutical precursor chemicals and preparations containing pharmaceutical precursor chemicals entrusted by overseas manufacturers for export. In accordance with the relevant requirements of the *Anti-Doping Regulations, the Decision of the State Council on Canceling and Adjusting the Sixth Batch of Administrative Approval Items* (GF [2012] No. 52) and the *Notice on Further Strengthening the Export Management of Overseas Contract Manufacturing of Protein Anabolic Preparations and Peptide Hormones* (SYJYHJ [2013] No. 226), where the exported pharmaceutical product manufacturers undertake the contract manufacturing of protein anabolic preparations and peptide hormones listed in the stimulant catalogue entrusted by overseas marketing authorization holders and applicants shall not organize production until obtaining an export license.

(2025-11-21)

（卫生部令第72号）有关要求，药品生产企业不得接受境外企业委托生产药品类易制毒化学品以及含药品类易制毒化学品的制剂并出口。依据《反兴奋剂条例》《国务院关于第六批取消和调整行政审批项目的决定》（国发〔2012〕52号）《关于进一步加强蛋白同化制剂、肽类激素境外委托生产出口管理的通知》（食药监药化监〔2013〕226号）有关要求，出口药品生产企业接受境外药品上市许可的持有者、申请者委托生产兴奋剂目录所列蛋白同化制剂、肽类激素的，应当在取得出口准许证后方可组织生产。

（2025-11-21）

Medical device

Announcement of the National Medical Products Administration on the Release of the *Good Manufacturing Practice for Medical Devices* ([2025] No. 107)

To strengthen the quality management of medical device manufacturing, regulate medical device manufacturing activities, promote normative development of the industry, and ensure the safety and effectiveness of medical devices for public use, the National Medical Products Administration has revised the Good Manufacturing Practice for Medical Devices in accordance with the Regulations for the Supervision and Administration of Medical Devices and the Provisions for Supervision and Administration of Medical Device Manufacturing. The revised GMP is hereby released and shall come into force as of November 1, 2026. The previous *Announcement on the Release of the Good Manufacturing Practice for Medical Devices* ([2014] No. 64) by the former China Food and Drug Administration (CFDA) shall be repealed simultaneously.

It is hereby announced.

National Medical Products Administration

November 4, 2025

(2025-11-04)

医疗器械

国家药监局关于发布医疗器械生产质量管理规范的公告（2025年第107号）

为加强医疗器械生产质量管理，规范医疗器械生产行为，促进行业规范发展，保障公众用械安全有效，根据《医疗器械监督管理条例》《医疗器械生产监督管理办法》等有关法规规章规定，国家药监局修订了《医疗器械生产质量管理规范》，现予发布，自2026年11月1日起施行，原国家食品药品监督管理总局《关于发布医疗器械生产质量管理规范的公告》（2014年64号）同时废止。

特此公告。

国家药监局

2025年11月4日

（2025-11-04）

Cosmetics

Requirements for the Pilot Program of Electronic Labels for Cosmetics

Article 1 To regulate the pilot program for electronic labels for cosmetics (including toothpaste, hereinafter referred to as "cosmetics"), these Requirements are formulated in accordance with the provisions of the Regulations on Supervision and Administration of Cosmetics (hereinafter referred to as the "Regulations"), the *Provisions for Registration and Filing of Cosmetics*, the *Provisions for Supervision and Administration of Manufacturing and Marketing of Cosmetics,* the *Provisions for*

化妆品

化妆品电子标签试点工作要求

第一条　为规范化妆品（含牙膏，下同）电子标签试点工作，根据《化妆品监督管理条例》（以下简称《条例》）《化妆品注册备案管理办法》《化妆品生产经营监督管理办法》《牙膏监督管理办法》《化妆品标签管理办法》等规定，制定本工作要求。

Toothpaste Regulation, and the *Measures for the Administration of Cosmetics Labels.*

Article 2 The term "cosmetics electronic label" (hereinafter referred to as "electronic label") as used in these Requirements refers to the relevant content of the Chinese label of cosmetics stored through a certain electronic storage mechanism, as well as the corresponding QR code generated through an information system. The electronic label shall have a convenient reading function, allowing consumers to directly read the product's Chinese label information by scanning the QR code with commonly used communication or payment software installed on their smartphones. The electronic label is an integral part of the cosmetics label.

Article 3 Enterprises participating in the electronic label pilot program (hereinafter referred to as "pilot enterprises") shall meet the following conditions:

(1) The entity shall be the registrant or filer of the cosmetics, or a domestic responsible person authorized by the cosmetics registrant or filer;

(2) The entity shall possess technical capabilities appropriate for the electronic label pilot program and have management personnel in place;

(3) The entity shall have a sound quality management system;

(4) The entity shall have the capability to implement the electronic label pilot program.

Article 4 Pilot enterprises shall generate electronic label QR codes and electronic label display content from product label information through an electronic label system.

The electronic label system may be constructed independently by pilot enterprises, by third-party technical institutions, or organized and constructed by provincial drug regulatory departments, with the specific method to be determined by provincial drug regulatory departments themselves.

Article 5 The electronic label system shall comply with the relevant requirements of the *Cybersecurity Law,* the *Data Security Law, the Personal Information Protection Law*, etc.; it shall have anti-tampering functions and establish a sound backup and recovery mechanism to ensure the accuracy, completeness, continuity, timeliness, accessibility, and traceability of data.

Article 6 The electronic label system shall cover key functions such as electronic label entry, management of QR code generation, scanning to obtain electronic labels, querying historical information of electronic labels, and querying structured information of electronic labels.

Article 7 The electronic label QR code generated by the electronic label system shall be marked with the words "Cosmetics Electronic Label" or "Toothpaste Electronic Label" in a prominent font below it (see Figures 1 and 2 for examples).

Article 8 The electronic label QR code shall be marked in a prominent position on the visible surface of the sales package. For products with an affixed Chinese label, the electronic label QR code shall be marked in a prominent position on the Chinese label.

The electronic label QR code shall be printed clearly, affixed firmly, and easily identifiable, with a size of not less than 9 mm × 9 mm in principle. The marking position of the electronic label QR code shall facilitate scanning and reading, and full consideration shall be given to the impact of label displacement, wrinkles, deformation, ink loss, etc., caused during storage and transportation on QR code readability.

For products with packaging boxes, pilot enterprises are encouraged to simultaneously use electronic labels on the packaging containers that are in direct contact with the product contents.

Article 9 The electronic label QR code and display content shall comply with the

第二条　本工作要求所称化妆品电子标签（以下简称“电子标签”），是指通过一定的电子化存储机制存储的化妆品中文标签相关内容，以及通过信息化系统生成的相应二维码。电子标签应当具备便捷识读功能，能够被消费者使用智能手机安装的常用通讯或者支付软件以扫码方式直接识读，获取产品中文标签信息。电子标签是化妆品标签的组成部分。

第三条　参与电子标签试点的企业（以下简称“试点企业”）应当符合以下条件：

（一）是化妆品注册人、备案人或者经化妆品注册人、备案人授权的境内责任人；

（二）具有与电子标签试点工作相适应的技术能力，并配备管理人员；

（三）具有完善的质量管理体系；

（四）具有开展电子标签试点工作的能力。

第四条　试点企业通过电子标签系统，将产品标签信息生成电子标签二维码和电子标签展示内容。

电子标签系统可由试点企业自行建设、第三方技术机构建设或者由省级药品监管部门组织建设，具体方式由省级药品监管部门自行确定。

第五条　电子标签系统应当符合《网络安全法》《数据安全法》《个人信息保护法》等相关要求；具备防篡改功能，并建立完善的备份与恢复机制，确保数据的准确性、完整性、连续性、及时性、可获得性和可追溯性。

第六条　电子标签系统应当覆盖电子标签录入、管理二维码生成、扫码获取电子标签、查询电子标签历史信息、查询电子标签结构化信息等主要功能。

第七条　电子标签系统生成的电子标签二维码应当在下方以醒目字体标注“化妆品电子标签”或者“牙膏电子标签”字样（示例详见图1、图2）。

第八条　电子标签二维码应当在销售包装可视面显著位置标注。加贴中文标签的，电子标签二维码应当在中文标签显著位置标注。

电子标签二维码应当印制清晰、粘贴牢固、容易辨认，原则上不小于9mm×9mm，电子标签二维码标注位置便于扫码识读，并充分

provisions of the Regulations and the *Measures for the Administration of Cosmetics Labels*, as well as the relevant requirements of the *Cosmetic Electronic Label Data Set* and the *Cosmetic Electronic Label QR Code Technical Specifications.*

Pilot enterprises shall ensure that the electronic label QR code meets technical requirements, and that the display content of the electronic label is true, accurate, and consistent with the relevant content of cosmetics registration and filing. The display content of the electronic label shall be easy to identify and read.

Article 10 The content of the electronic label shall be directly displayed on the page after scanning the code, without any additional display conditions or interfering factors such as pop-ups that affect normal reading. Pilot enterprises shall fully display the mandatory labeling content specified in Article 7 of the *Measures for the Administration of Cosmetics Labels* in the electronic label, and other displayed content shall not exceed the content specified in the product label sample.

Pilot enterprises may, through a hyperlink, display content such as product anti-counterfeiting, traceability information, and the URL link to the official product promotion page on the secondary page after scanning the code, and clearly mark "The content displayed on this page is not part of the cosmetics electronic label information and shall be the sole responsibility of the enterprise". It is encouraged that the electronic label system be equipped with functions such as text enlargement and voice broadcasting for the displayed content of the electronic label to facilitate consumers' identification and reading.

Pilot enterprises shall, in accordance with consumers' needs, provide consumers with complete Chinese label information of the product in written or electronic form through on-site provision, mail, e-mail, and other methods.

Article 11 For cosmetics whose Chinese product labels are marked by means of electronic labels, in addition to the electronic label QR code, the following content shall be marked in standardized Chinese characters at least on the visible surface of the product's sales package:

(1) Chinese product name and special cosmetics registration certificate number;

(2) Name of the registrant/filer;

(3) Net content;

(4) Shelf life;

(5) Safety warning statements required to be marked by laws, regulations, mandatory national standards, and technical specifications;

(6) Children's cosmetics shall be marked with the children's cosmetics symbol.

For small-specification packaged products with a net content not exceeding 15 g or 15 ml, the physical label may be exempted from marking the content specified in item (5) above.

Article 12 Before cosmetics using electronic labels are marketed for sale, pilot enterprises shall upload the electronic label URL data structure code information, the displayed content of the electronic label, and images of the product's sales packaging marked with the electronic label to the Cosmetics Registration and Filing Information Service Platform. Pilot enterprises shall generate the electronic label URL data structure coding information in accordance with the requirements of the *Cosmetic Electronic Label QR Code Technical Specifications*, and the uploaded electronic label URL data structure coding information shall be specific to the product identification unit.

In the event of any change in the electronic label information, pilot enterprises shall upload the relevant information of the proposed changes to the electronic label to the Cosmetics

考虑储运过程造成的标识位移、褶皱、变形、脱墨等对二维码识读造成的影响。

对于具有包装盒的产品，鼓励试点企业在直接接触产品内容物的包装容器上同时使用电子标签。

第九条　电子标签二维码和展示内容应当符合《条例》《化妆品标签管理办法》的规定，并符合《化妆品电子标签数据集》《化妆品电子标签二维码技术规范》的相关要求。

试点企业应当确保电子标签二维码符合技术要求，电子标签的展示内容真实、准确并与化妆品注册备案的相关内容一致。电子标签的展示内容应当易于辨认、识读。

第十条　电子标签的内容应当在扫码后的页面直接展示，不得附加展示条件，不得有影响正常阅读的弹窗等干扰因素。试点企业应当在电子标签中完整展示《化妆品标签管理办法》第七条规定必须标注的内容，展示的其他内容不得超出产品标签样稿载明的内容。

试点企业可以通过跳转链接的方式，在扫码后的二级页面展示产品防伪、追溯等内容以及产品官方网站宣传页面的网址链接，并明确标注“此页面展示内容不属于化妆品电子标签信息，由企业自行负责”。鼓励电子标签系统设置电子标签展示内容文字放大、语音播报等功能，便于消费者辨认和识读。

试点企业应当根据消费者需求，通过现场提供、邮寄、电子邮件等方式，为消费者提供书面或者电子形式的完整产品中文标签信息。

第十一条　以电子标签方式标注产品中文标签的化妆品，除电子标签二维码外，应当在产品销售包装可视面使用规范汉字至少标注以下内容：

（一）产品中文名称和特殊化妆品注册证书编号；

（二）注册人、备案人名称；

（三）净含量；

（四）使用期限；

（五）法律法规、强制性国家标准和技术规范要求标注的安全警示用语；

（六）儿童化妆品应当标注儿童化妆品标志。

Registration and Filing Information Service Platform before the cosmetics using the changed electronic label are marketed for sale.

Article 13 Cosmetics registrants, filers, and domestic responsible persons shall be responsible for the legitimacy, accuracy, completeness, continuity, timeliness, accessibility, and traceability of the electronic label. If an electronic label system constructed by a third-party technical institution is used, pilot enterprises shall sign an agreement with the third-party technical institution, defining the respective rights, obligations, and responsibilities of both parties, as well as the content of the extended inspections that the third-party technical institution shall proactively accept from drug regulatory departments at all levels.

Article 14 Pilot enterprises shall ensure that the electronic label can display the label information in real time and that the code scanning and reading function is continuous and uninterrupted. If there is a temporary obstacle to the code scanning and reading function, pilot enterprises shall repair and rectify it as soon as possible. For products using electronic labels that are no longer manufactured or imported, pilot enterprises shall ensure that the displayed content of their electronic labels is normally displayed for 1 year after the expiration of the shelf life of the last batch of manufactured or imported products; for products with a shelf life of less than 1 year, the displayed content of their electronic labels shall be normally displayed for no less than 2 years.

If the code scanning and reading function of the electronic label experiences malfunctions for a long time, pilot enterprises shall take timely remedial measures to ensure that consumers can obtain complete cosmetics label information. If remedial measures cannot be taken and the malfunction has caused cosmetic quality defects or other problems that may endanger human health, the manufacturing shall be stopped immediately, and the cosmetics using electronic labels that have been put on the market for sale shall be recalled.

Article 15 Drug regulatory departments at or above the county level shall be responsible for the daily supervision of electronic labels, and may conduct extended inspections on the entities responsible for the construction, operation, and maintenance of the electronic label systems when necessary. Violations of relevant laws and regulations regarding cosmetics label management shall be handled in accordance with the relevant laws and regulations:

(1) If the labeled content on the sales packaging of cosmetics using electronic labels or the displayed content of the electronic label does not comply with the requirements of the Regulations, it shall be handled in accordance with item (5) of Article 61 of the Regulations;

(2) If pilot enterprises fail to submit the relevant electronic label information to the Cosmetics Registration and Filing Information Service Platform as required, the drug regulatory department shall order corrective actions;

(3) If the electronic label is printed unclearly, difficult to scan and read, or not firmly affixed, but does not affect product quality or safety and will not mislead consumers, it shall be handled in accordance with the second paragraph of Article 61 of the Regulations.

Article 16 Provincial drug regulatory departments participating in the pilot program shall supervise and guide pilot enterprises to carry out the pilot work as required. If a pilot enterprise is found to have seriously violated these Requirements, its pilot qualification shall be suspended. Enterprises whose pilot qualification has been suspended shall complete the rectification within a time limit, and shall not use electronic labels in new

净含量不大于15g或者15ml的小规格包装产品，实物标签可免于标注上述第（五）项内容。

第十二条　使用电子标签的化妆品上市销售前，试点企业应当在化妆品注册备案信息服务平台上传电子标签网址数据结构编码信息、电子标签的展示内容以及标注电子标签的产品销售包装图片等资料。试点企业应当按照《化妆品电子标签二维码技术规范》要求生成电子标签网址数据结构编码信息，上传的电子标签网址数据结构编码信息应当具体到产品标识单元。

电子标签信息发生变更的，试点企业应当在使用变更后电子标签的化妆品上市销售前，在化妆品注册备案信息服务平台上传拟变更的电子标签相关信息。

第十三条　化妆品注册人、备案人、境内责任人对电子标签的合法性、准确性、完整性、连续性、及时性、可获得性和可追溯性负责。使用第三方技术机构建设的电子标签系统的，试点企业应当与第三方技术机构签署协议，明确双方各自承担的权利、义务和责任，以及第三方技术机构主动接受各级药品监管部门对其进行延伸检查的内容。

第十四条　试点企业应当保障电子标签能够实时展示标签信息并保障扫码识读功能连续不间断，扫码识读功能出现暂时性障碍的，试点企业应当尽快修复整改。使用电子标签的产品不再生产或者进口的，试点企业应当保障其电子标签的展示内容在最后一批生产、进口的产品使用期限届满后1年内正常显示；使用期限不足1年的产品，应当保障其电子标签的展示内容正常显示时间不得少于2年。

对于电子标签扫码识读功能出现障碍且持续时间较长的，试点企业应当及时采取补救措施，确保消费者能够获取完整的化妆品标签信息。对于无法采取补救措施，已造成化妆品质量缺陷或者其他问题、可能危害人体健康的，应当立即停止生产并召回已经上市销售的使用电子标签的化妆品。

第十五条　县级以上药品监管部门负责电子标签的日常监管，必要时对电子标签系统建设运维主体进行延伸检查。发现违反化妆品标签管理相关法规规定的，依照相关法规规定处理：

products or add electronic labels to products already on the market before the completion of the rectification. If the rectification is not completed within the specified time limit or if the enterprise still does not meet the requirements after rectification, the electronic label pilot qualification shall be revoked.

Enterprises whose pilot qualification has been revoked shall stop manufacturing, importing, and selling cosmetics using electronic labels from the date of revocation of the qualification.

(2025-10-20)

（一）发现使用电子标签的化妆品销售包装标注内容或者电子标签的展示内容不符合《条例》要求的，依照《条例》第六十一条第（五）项规定处理；

（二）发现试点企业未按要求在化妆品注册备案信息服务平台中提交电子标签有关信息的，由药品监管部门责令改正；

（三）发现电子标签印制不清晰难以扫描识读或者粘贴不牢的，不影响产品质量安全且不会对消费者造成误导的，依照《条例》第六十一条第二款规定处理。

第十六条　参与试点的省级药品监管部门应当督促指导试点企业按要求开展试点工作，发现试点企业严重违反本工作要求的，应当暂停试点企业的试点资格。被暂停试点资格的企业应当限期完成整改，整改完成前不得在新产品中使用电子标签或者在已上市产品中增加使用电子标签。在规定期限内未完成整改或者整改后仍不符合要求的，取消电子标签试点资格。被取消试点资格的企业，自取消资格之日起，应当停止生产、进口、销售使用电子标签的化妆品。

（2025-10-20）

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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