2026 Volume 2

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Announcement of the National Medical Products Administration on Matters Concerning Further Optimizing Review and Approval of Overseas-Marketed Drugs in Clinical Urgent Need ([2026] No. 3)

In order to accelerate the marketing of overseas-marketed drugs in China in clinical urgent need and meet patients' urgent clinical medication needs, the National Medical Products Administration (NMPA) decided to further optimize the working mechanism for review and approval of overseas-marketed drugs in clinical urgent need. The relevant matters are hereby announced as follows.

I. Uphold the clinical value-oriented principle, encourage applicants to conduct global simultaneous R&D and concurrent marketing application in China, and encourage domestic applications for overseas-marketed originator drugs and generic drugs in clinical urgent need. The aforementioned drugs that meet the requirements may be included in the scope of priority review designation.

II. Optimize the review mechanism to expedite the review efficiency. Applicants may apply for a Type I communication for overseas-marketed drugs in clinical urgent need regarding the use of domestic and overseas clinical data, priority review and conditional approval applications, and submit materials supporting clinical urgency, including study data supporting overseas registration and marketing (all clinical data and necessary pharmaceutical, non-clinical, and other study data), post-marketing clinical application and safety surveillance reports overseas, benefit-risk assessment for cross-ethnic/regional application, and post-import marketing risk control plans (including post-marketing clinical study plans), etc. The submission of Multi-Regional Clinical Trial (MRCT) data from studies conducted in China is encouraged. After reaching a consensus through communication with the Center for Drug Evaluation of NMPA (CDE), applicants shall submit a clinical trial application for products requiring drug clinical trials, and CDE shall make a decision within 30 days from the date of acceptance. For drugs eligible for clinical trial exemption, the marketing authorization application may be directly submitted. For products that apply for priority review designation, CDE shall review in accordance with relevant procedures and include them in the scope of priority review designation if they meet the requirements upon expert comments. CDE shall implement separate management for registration applications of the overseas-marketed drugs in clinical urgent need, which are included in the scope of priority review designation, and strengthen communication and instruction.

III. Improve the testing system according to the characteristics of products. For the rare disease drugs in clinical urgent need that are marketed overseas but not in China, applicants are encouraged to apply for registration testing on a pre-submission basis. If only the sample testing is required, the time limit for registration testing shall be shortened from 60 days to 40 days; if both specification verification and sample testing are required at the same time, the time limit for registration

国家药监局关于进一步优化临床急需境外已上市药品审评审批有关事项的公告（2026年第3号）

为加快临床急需境外已上市药品在境内上市，满足患者临床用药迫切需求，国家药监局决定进一步优化临床急需境外已上市药品审评审批工作机制。有关事项公告如下。

一、坚持以临床价值为导向，鼓励申请人在中国开展全球同步研发、同步申报上市；鼓励临床急需境外已上市的原研药及仿制药在境内申报，对于符合要求的可纳入优先审评审批范围。

二、优化审评机制，加快审评速度。申请人可对临床急需的境外已上市药品就境内外临床数据利用情况、优先审评审批事项及附条件申请事项，申请Ⅰ类沟通交流，并提交支持临床急需的资料，包括支持境外注册上市的研究数据（包括全部临床资料以及必要的药学、非临床及其他研究资料），境外上市后临床应用情况及安全性监测报告，跨种族/地域应用的获益风险评估分析，进口上市后的风险控制计划（包括上市后临床研究计划）等，鼓励提交在国内开展的国际多中心药物临床试验研究资料。经与国家药品监督管理局药品审评中心（以下简称药审中心）沟通交流形成一致意见后，对于需要开展药物临床试验的品种，申请人需递交临床试验申请，药审中心自受理之日起30日内决定是否同意开展临床试验；对于可豁免药物临床试验的品种，申请人可直接提出药品上市许可申请。对于申请纳入优先审评审批程序的品种，药审中心按程序审核，经专家评估符合要求的，可纳入优先审评审批范围。

药审中心对纳入优先审评审批范围的临床急需境外已上市药品注册申请予以单独管理，加强沟通指导。

三、完善检验制度，体现品种特点。对于临床急需境外已上市境内未上市的罕见病药品，鼓励申请人采取前置检验方式申请注册检验。只进行样品检验的，注册检验时限由60日缩短至40日；同时进行标准复核和样品检验的，注

Published by
China Center for Food and Drug International Exchange

testing shall be shortened from 90 days to 70 days. The sample quantity required for registration testing is one commercial-scale batch, and the number of samples per batch is twice the number of samples required for specification testing items. For rare disease drugs with extremely low batch yield, applicants may jointly determine the minimum number of samples required for registration testing items with the testing institutions.

IV. Optimize registration inspection with a risk-based approach. For products included in the scope of priority review designation, the initiation modes of overseas registration inspection shall be optimized. Holistically arrange the registration inspection and post-marketing overseas inspection tasks based on risk level, and on-site or remote inspection and other modes may be adopted as determined by risks.

V. Continuously facilitate the temporary import channels for drugs in clinical urgent need. The temporary import pathways for rare disease drugs shall be optimized to further improve efficiency and accelerate the process to meet the clinical urgent medication needs of medical institutions for rare disease drugs.

It is hereby announced.

National Medical Products Administration

January 5, 2026

(January 7, 2026)

册检验时限由90日缩短至70日。注册检验所需样品量为商业规模生产1批次，每批样品数量为质量标准检验项目所需量的2倍；对于单批次产量极低的罕见病药品，申请人可与检验机构共同研究确定注册检验项目所需最少样品数量。

四、优化注册核查，突出风险导向。对纳入优先审评审批范围的，优化境外注册核查启动方式，可根据风险将注册核查和上市后境外检查工作有机结合、统筹安排，并基于风险确定现场检查或远程检查等方式的运用。

五、持续畅通临床急需药品临时进口通道。优化罕见病临时进口路径，进一步提速增效，满足医疗机构临床急需罕见病用药需求。

特此公告。

国家药监局

2026年1月5日

（2026-01-07）

Policy Interpretation of the *Announcement of the National Medical Products Administration on Matters Concerning Further Optimizing Review and Approval of Overseas-marketed Drugs in Clinical Urgent Need*

I. What is the background for the issuance of this policy?

Since the implementation of the drug review and approval system reform in 2015, the National Medical Products Administration (NMPA) has continuously optimized the review and approval processes, taking multiple measures to promote the simultaneous research and marketing of overseas new drugs. In July 2020, the *Working Procedures for Priority Review and Approval of Drug Marketing Authorization (Trial)* was released and implemented, improving the priority review and approval system for drugs. It explicitly stipulated that six categories of drugs, including innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases, could be included in the scope of priority review and approval.

In 2018, NMPA and the National Health Commission jointly issued the *Announcement on Issues Pertaining to the Review and Approval of Overseas New Drugs Catering to Clinical Urgent Need* (No. 79, 2018), clearly including overseas-marketed drugs in clinical urgent need into the scope of priority review and approval. After the release of Announcement No. 79, three lists of overseas new drugs in clinical urgent need were published, comprising 81 products in total. To date, 55 products have been approved for marketing through the priority review and approval process, effectively promoting the introduction of overseas-marketed drugs in clinical urgent need and playing a positive role in meeting clinical medication needs.

In recent years, with the continuous deepening of reforms and the increasing needs for medication among the public, there have been calls from the industry to further expand the scope of the current priority review and approval process, enabling more good overseas-marketed drugs to be quickly introduced to China. For example, clinically

《国家药监局关于进一步优化临床急需境外已上市药品审评审批有关事项的公告》政策解读

一、政策出台背景是什么？

2015年药品审评审批制度改革实施以来，国家药监局持续优化审评审批流程，采取多项举措，促使境外新药同步研发上市。2020年7月发布实施《药品上市许可优先审评审批工作程序（试行）》，完善了药品优先审评审批制度，明确防治重大传染病和罕见病等疾病的创新药和改良型新药等六种情形可纳入优先审评审批范围。

2018年，国家药监局与国家卫生健康委员会联合发布了《关于临床急需境外新药审评审批相关事宜的公告》（2018年第79号），明确将临床急需的境外已上市新药纳入优先审评审批范围。79号公告发布后，先后发布了3批临床急需境外新药名单，共81个品种。目前，已有55个品种通过优先审评审批程序批准上市，有效促进了临床急需境外已上市新药引进，在满足临床用药需求方面发挥了积极作用。

近年来，随着改革的不断深入，人民群众用药需求的不断增加，业界呼吁能够进一步拓展现行优先审评审批的范围，使得更多境外已上市好药能快速引进中国。例如，境外已上市境内未上市的临床急需的治疗慢性病、老年病等药品，也可纳入优先审评审批范围。

urgent drugs for the treatment of chronic diseases, elderly diseases, etc., which are marketed overseas but not yet available in China, may also be included in the scope of priority review and approval.

In order to further encourage more overseas-marketed drugs in clinical urgent need to enter the Chinese market and benefit domestic patients, NMPA has researched and drafted the *Announcement of NMPA on Matters Concerning Further Optimizing Review and Approval of Overseas-marketed Drugs in Clinical Urgent Need* (hereinafter referred to as the *Announcement*). This *Announcement* takes comprehensive measures such as expanding the scope of priority review and approval, fully utilizing domestic and international clinical research data, optimizing testing processes, and improving registration inspections to promote the entry of more overseas-marketed drugs into China in clinical urgent need.

II. What is the relationship between this *Announcement* and Announcement No. 79?

Announcement No. 79 played a positive role in rapidly introducing overseas-marketed drugs in clinical urgent need. Its procedures have been incorporated and encompassed into the 2020 *Working Procedures for Priority Review and Approval of Drug Marketing Authorization (Trial)*. The three batches of product lists selected by No. 79 remain valid, and applicants can continue to apply for the products on these lists, which can still be included in the current priority review and approval scope. For products not included in the three product lists, starting from the issuance of this *Announcement*, applicants may submit applications, and those meeting the requirements may be included in the priority review and approval scope. Therefore, this *Announcement* and Announcement No. 79 are complementary and do not conflict.

III. Will a catalog of overseas-marketed products in clinical urgent need be released?

The method of publishing a catalog of products is difficult to adapt to the rapid changes in drug research and development, innovation, and clinical needs. Therefore, this *Announcement* adopts a flexible working mechanism. Through enterprise applications, review by the Center for Drug Evaluation (CDE) of NMPA, and necessary expert evaluations, it adapts to the constantly changing clinical demands.

IV. Do generic drugs need to conduct clinical trials?

For overseas-marketed generic drug products, there are differences in whether clinical trials have been conducted when they were marketed overseas. Applications submitted in accordance with this *Announcement* that, after evaluation, meet the requirements may be exempted from clinical trials.

V. How will the testing of overseas-marketed drugs in clinical urgent need be optimized?

In July 2025, the National Institutes for Food and Drug Control (NIFDC) issued the *Drug Registration Inspection Work Procedures and Technical Requirements Specification (2025 Revised Edition)*, introducing several measures to facilitate enterprises, such as reducing the required test quantity per batch of drug registration testing from 3 times to 2 times, and allowing applicants to use the reserved samples from the initial test for registration testing in response to supplementation during review. For overseas-marketed drugs in clinical urgent need included in the priority review and approval scope, testing institutions shall implement a priority testing process, shortening the testing timeline by 10 working days.

For overseas-marketed rare disease drugs with a short shelf life, extremely low batch production, and clinical urgency, import testing institutions will optimize the import testing strategy. Based on the product's full self-inspection report, only key quality control items and indicators that may be affected

为进一步鼓励更多临床急需的境外新药、好药进入我国市场，惠及国内患者，国家药监局研究起草《关于进一步优化临床急需境外已上市药品审评审批有关事项的公告》（以下简称《公告》），通过采取拓宽优先审评审批范围、充分利用境内外临床研究数据、优化检验流程、优化注册核查等改革举措综合施策，促使更多临床急需的境外已上市新药、好药进入我国市场。

二、本《公告》与79号公告的关系是什么？

79号公告对于快速引进临床急需的境外已上市新药起到了积极的推动作用，其工作程序已被2020年《药品上市许可优先审评审批工作程序（试行）》所吸纳涵盖，其遴选出的3批品种清单仍然有效，申请人继续申报清单中的品种，仍可纳入现行优先审评审批范围。对于不在3批品种清单中的品种，自本《公告》发布之日起，申请人可以提出申请，符合条件的，可以纳入优先审评审批范围。因此，本《公告》与79号公告不冲突，互为补充。

三、是否会发布临床急需境外已上市品种目录？

发布品种目录的方式难以适应药品研发创新及临床需求的快速变化。因此，本《公告》采取灵活的工作机制，通过企业申请、国家药监局药品审评中心审评及必要的专家评估，来适应不断变化的临床需求。

四、仿制药需要开展临床试验吗？

对于境外已上市仿制药品种，其在境外上市时是否已开展临床试验的情况存在差异，按本《公告》提出申请的，经评估符合要求的，可豁免临床试验。

五、如何优化临床急需境外已上市药品的检验？

2025年7月，中国食品药品检定研究院发布《药品注册检验工作程序和技术要求规范（2025年修订版）》，提出将药品注册检验每批次3倍检验量调减为2倍，允许申请人调用首次检验的留样用于审评中发补的注册检验等多项便利企业的措施。对于纳入优先审评审批范围的临床急需境外已上市药品，检验机构实施优先检验程序，检验时限缩短10个工作日。

对于使用效期短、批产量极低、临床急需境外已上市罕见病药品的进口检验，检验机构将优化进口检验策略，基于产品全项自检报告，根据产品特性，仅考察质量控制关键项目和可能受储运过程影响的指标，不进行全项检验。具体数量

during storage and transportation will be tested, and full-item testing will not be conducted. The specific quantity and testing items will be jointly determined by the NIFDC or the port inspection institution and the applicant.

VI. What specific measures are included to optimize the temporary import channels?

To optimize the temporary import pathway for rare diseases and further accelerate efficiency, NMPA, in collaboration with the National Health Commission, will optimize relevant procedures in the pilot work zone for rare disease drug guarantees in Beijing. The city has already issued relevant implementation measures. By adopting measures such as changing the expert evaluation process from serial to parallel and allowing multiple uses of the same customs clearance, the clinical urgent medication needs of rare disease patients can be met more quickly.

(January 7, 2026)

和检验项目由中国食品药品检定研究院或口岸检验机构与申请人共同研究确认。

六、优化临时进口通道的具体举措包括哪些？

为优化罕见病临时进口路径，进一步提速增效，国家药监局会同国家卫生健康委，在北京市罕见病药品保障先行区的试点工作中，对相应程序进行优化，北京市已经出台了相关实施办法，通过采取将专家评估流程从串联改为并联、一次通关多次使用等举措，更加快速地满足罕见病患者的临床急需用药需求。

（2026-01-07）

Announcement of the National Medical Products Administration on the Implementation of Unique Device Identification for Medical Devices in Specific Circumstances（[2026] No. 15）

To further implement the *Regulations for the Supervision and Administration of Medical Devices, the Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry,* and the key tasks of the State Council concerning the deepening of the reform of the medical and health system, and to better guide the implementation of the Unique Device Identification (UDI) system for medical devices, the relevant matters concerning the implementation of UDI for medical devices in specific circumstances are hereby announced as follows:

I. Circumstances for exemption from UDI implementation

Exemption from UDI implementation refers to the exemption from the creation, coding, and database submission of the UDI in accordance with the requirements of the *Rules for Unique Device Identification System* (hereinafter referred to as the *Rules*).

(1) Except for implanted medical devices classified under classification codes 12-XX or 13-XX, where the smallest sales unit package of a medical device contains multiple single-use medical devices with the same specification, model, and production batch number, and the smallest sales unit package has already been assigned a UDI, the individual medical devices within the smallest sales unit package may be exempted from UDI implementation. Examples include condoms, blood collection tubes, and medical masks contained in the smallest sales unit package.

(2) Customized medical devices, as defined in the *Provisions on the Supervision and Administration of Customized Medical Devices (Trial),* may be exempted from UDI implementation.

(3) If a medical device combination package is assigned a UDI as a whole, and the single-use medical devices contained therein are only used under the condition of the medical device combination package, the single-use medical devices in the medical device combination package may not be assigned a UDI. If a medical device contained in a medical device combination package is already exempted from

国家药监局关于特定情形实施医疗器械唯一标识有关事项的公告（2026年第15号）

为进一步贯彻落实《医疗器械监督管理条例》《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》和国务院深化医药卫生体制改革有关重点工作任务，更好地指导医疗器械唯一标识实施，现就特定情形实施医疗器械唯一标识的有关事项公告如下：

一、免于实施医疗器械唯一标识的情形

免于实施医疗器械唯一标识，是指免于按照《医疗器械唯一标识系统规则》（以下简称《规则》）的要求开展医疗器械唯一标识的创建、赋码和数据库提交。

（一）除分类编码为12-XX或13-XX的植入医疗器械外，如医疗器械最小销售单元包装中包含多个相同规格型号及生产批号的一次性使用医疗器械，且医疗器械的最小销售单元已赋予医疗器械唯一标识，则最小销售单元包装中的单个医疗器械可免于实施医疗器械唯一标识。例如最小销售单元包装中的避孕套、采血管、口罩等。

（二）《定制式医疗器械监督管理规定（试行）》中规定的定制式医疗器械可免于实施医疗器械唯一标识。

（三）如医疗器械组合包整体具有医疗器械唯一标识，且其所含一次性使用医疗器械只在医疗器械组合包条件下使用，则医疗器械组合包中的一次性使用医疗器械可无需赋予医疗器械唯一标识。如医疗器械组合包中的医疗器械，其本身已免于实施医疗器械唯一标识，则其包

the implementation of UDI, it shall not be assigned a UDI when included in the medical device combination package.

(4) Transportation packaging of medical devices may be exempted from the implementation of UDI.

(5) Medical devices intended only for export and not for sale or use in China may be exempted from implementation of UDI, but shall comply with the requirements of the importing country (region).

(6) Drug-led drug-device combination products may be exempted from the implementation of UDI on the premise that the drugs are traceable.

(7) Where a drug and a single-use medical device are packaged together as one smallest sales unit, and the medical device is described in the drug package insert, and the smallest sales unit bears a drug traceability code, the single-use medical device in the package may not be assigned a UDI.

II. Implementation requirements for other specific circumstances

(1) For reusable medical devices that require reprocessing before each use, UDI shall be applied directly to the device body to ensure the product can be uniquely identified before each use. If directly marking UDI on the device body may affect the safety and effectiveness of the product or is technically infeasible, UDI may not be directly marked on the device body; however, the medical device registrant or filer shall mark UDI on the smallest sales unit package of the product and provide other effective schemes for identification and traceability for reuse.

(2) Reusable surgical devices regulated as Class I medical devices may not be required to bear the Production Identifier (UDI-PI) under the UDI system, but shall bear the Device Identifier (UDI-DI) under the UDI system.

(3) For standalone software provided through non-physical media, a physical UDI data carrier may not be required, but UDI shall be provided in an easily readable plain text format on a user-visible interface of the software; for standalone software without a user interface, UDI shall be transmitted via Application Programming Interface (API).

The electronic display content of UDI for standalone software only needs to provide the human-readable part (including data separators).

III. Other Matters

(1) For medical device products eligible for exemption from implementation of UDI, medical device registrants or filers may decide whether to conduct creation and assignment of UDI in accordance with the requirements of the Rules and upload relevant data to the UDI database based on their actual needs. Specifically, products for which UDI has been implemented in accordance with the requirements of the Rules may independently choose to continue or discontinue implementation, and the product information already published in the UDI database shall remain published.

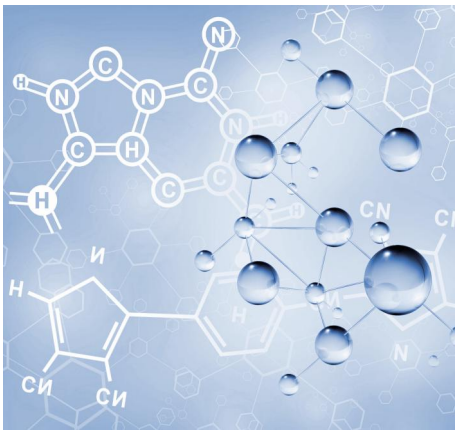
(2) The NMPA may adjust the requirements for implementation of UDI according to the needs of medical device regulation.

It is hereby announced.

National Medical Products Administration

January 23, 2026

(March 13, 2026)



含在医疗器械组合包中时也无需赋予医疗器械唯一标识。

（四）医疗器械的运输包装可免于实施医疗器械唯一标识。

（五）仅用于出口，不在国内销售使用的医疗器械可免于实施医疗器械唯一标识，但应当符合进口国（地区）的要求。

（六）以药品为主的药械组合产品在药品可追溯的前提下，可免于实施医疗器械唯一标识。

（七）对于药品和一次性使用医疗器械共同包装作为一个最小销售单元，在药品说明书中包含该器械，且该最小销售单元有药品追溯码的前提下，其包装中的一次性使用医疗器械可无需赋予医疗器械唯一标识。

二、其他特定情形实施要求

（一）对于重复使用且每次使用前需要再处理的医疗器械，应当采用本体直接标识医疗器械唯一标识的赋码方式，确保产品在每次使用前可被唯一性识别。若在其本体上直接标记医疗器械唯一标识可能会影响该产品的安全有效性或者从技术角度难以实现，则可不在其本体上直接标记医疗器械唯一标识，但医疗器械注册人、备案人应在其最小销售单元包装上标记医疗器械唯一标识并提供其他能有效识别、追溯重复使用的方案。

（二）按照第一类医疗器械管理的重复使用手术器械，可无需具有医疗器械唯一标识中的生产标识（UDI-PI），但应当具有医疗器械唯一标识中的产品标识（UDI-DI）。

（三）对于采用非物理介质提供的独立软件，可无需具备实体的医疗器械唯一标识数据载体，但应当采用易读的纯文本格式，在软件用户易见的界面上提供医疗器械唯一标识；对于没有用户界面的独立软件，应当能够通过应用程序编程接口（API）来发送医疗器械唯一标识。

独立软件的医疗器械唯一标识电子显示内容，只需提供人工识读部分（包括数据分隔符）。

三、其他事项

（一）对于符合免于实施医疗器械唯一标识的医疗器械产品，医疗器械注册人、备案人可以结合自身实际需要决定是否按照《规则》的要求开展医疗器械唯一标识的创建和赋码，并将相关数据上传至医疗器械唯一标识数据库；其中，已按照《规则》要求实施唯一标识的，可以自主选择继续实施或者不再实施唯一标识，医疗器械唯一标识数据库中已经公开的产品信息将保持公开。

（二）国家药监局可以根据医疗器械监管需要，对医疗器械唯一标识实施要求进行调整。

特此公告。

国家药监局

2026年1月23日

（2026-03-13）

Announcement of the National Medical Products Administration, the National Health Commission and the National Healthcare Security Administration on Effectively Implementing Unique Device Identification for Subsequent Medical Device Products（[2026] No. 21）

To further implement the *Regulations for the Supervision and Administration of Medical Devices, the Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry,* and the relevant key tasks of the State Council on deepening the reform of the medical and health system, and, on the basis of implementing Unique Device Identification (UDI) for all Class III medical devices (including in vitro diagnostic reagents) and 103 Class II medical device products, the relevant work on implementing UDI for subsequent medical device products is hereby announced as follows:

I. Scope of products

Medical device products for which the implementation of UDI is specified in the *Announcement of the National Medical Products Administration, the National Health Commission and the National Healthcare Security Administration on Further Advancing the Pilot Program and Effectively Implementing UDI for the First Batch of Medical Devices* (No. 106, 2020), the *Announcement of the National Medical Products Administration, the National Health Commission and the National Healthcare Security Administration on Effectively Implementing UDI for the Second Batch of Medical Devices* (No. 114, 2021), and the *Announcement of the National Medical Products Administration, the National Health Commission and the National Healthcare Security Administration on Effectively Implementing UDI for the Third Batch of Medical Devices* (No. 22, 2023) shall be excluded.

II. Schedule arrangements

Medical device registrants or filers shall carry out the following work in an orderly manner as required.

(1) UDI assignment

All Class II medical devices (including in vitro diagnostic reagents) and all Class I in vitro diagnostic reagents manufactured on or after June 1, 2027 shall be assigned UDI. The above products manufactured before June 1, 2027 may be exempted from UDI assignment.

All Class I medical devices manufactured on or after June 1, 2029 shall be assigned UDI. The above products manufactured before June 1, 2029 may be exempted from UDI assignment.

(2) Submission of device identifier to the registration/filing administration system

For applications for registration/filing submitted on or after the corresponding implementation date, medical device registration applicants or filers shall submit the device identifier of the smallest sales unit of their products in the registration/filing administration system. For products for which registration has been accepted or approved before the corresponding implementation date, registrants shall submit the device identifier of the smallest sales unit of their products in the registration system at the time of product registration renewal or registration change. For products for which filing has been completed before the corresponding implementation date, filers shall submit the device identifier of the smallest sales unit of their products in the filing system at the time of product filing change.

The device identifier shall not be subject to registration/filing review, and independent changes to the device identifier shall not fall within the scope of registration/filing changes.

国家药监局　国家卫生健康委　国家医保局关于做好后续品种实施医疗器械唯一标识工作的公告（2026年第21号）

为进一步贯彻落实《医疗器械监督管理条例》《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》和国务院深化医药卫生体制改革有关重点工作任务，在所有第三类医疗器械（含体外诊断试剂）和103种第二类医疗器械实施医疗器械唯一标识基础上，现就后续品种实施医疗器械唯一标识有关工作公告如下：

一、品种范围

除《国家药监局 国家卫生健康委 国家医保局关于深入推进试点做好第一批实施医疗器械唯一标识工作的公告》（2020年第106号）、《国家药监局 国家卫生健康委 国家医保局关于做好第二批实施医疗器械唯一标识工作的公告》（2021年第114号）、《国家药监局　国家卫生健康委　国家医保局关于做好第三批实施医疗器械唯一标识工作的公告》（2023年第22号）规定实施医疗器械唯一标识的医疗器械品种。

二、进度安排

医疗器械注册人、备案人应当按照要求有序开展以下工作：

（一）唯一标识赋码

2027年6月1日起生产的全部第二类医疗器械（包括体外诊断试剂）和全部第一类体外诊断试剂应当具有医疗器械唯一标识。2027年6月1日前生产的上述品种产品可不具有唯一标识。

2029年6月1日起生产的全部第一类医疗器械应当具有医疗器械唯一标识。2029年6月1日前生产的上述品种产品可不具有唯一标识。

（二）产品标识注册/备案管理系统提交

相应实施日期之日起申请注册/备案的，医疗器械注册申请人、备案人应当在注册/备案管理系统中提交其产品最小销售单元的产品标识。相应实施日期之日前已受理或者获准注册的，注册人应当在产品延续注册或者变更注册时，在注册系统中提交其产品最小销售单元的产品标识；相应实施日期之日前已备案的，备案人应当在产品变更备案时，在备案系统中提交其产品最小销售单元的产品标识。

产品标识不属于备案/注册审查事项，产品

(3) Submission to the UDI database

For all Class II medical devices (including in vitro diagnostic reagents) and all Class I in vitro diagnostic reagents manufactured on or after June 1, 2027, and all Class I medical devices manufactured on or after June 1, 2029, medical device registrants or filers shall upload the device identifier and relevant data of the smallest sales unit and higher-level packaging to the UDI database in accordance with relevant standards or specifications prior to product marketing, to ensure the data are authentic, accurate, complete, and traceable. For medical devices whose information has been maintained in the healthcare security classification and code databases of the National Healthcare Security Administration, such as the Healthcare Security Medical Consumables Database and the Healthcare Security In Vitro Diagnostic Reagents Database, the corresponding fields for healthcare security classification and codes (including those for medical consumables, in vitro diagnostic reagents, etc.) shall be supplemented in the UDI database. Meanwhile, UDI-related information shall be supplemented in the maintenance of the aforementioned healthcare security classification and code databases, and consistency with the data in the UDI database shall be verified.

Where relevant data of the device identifier of the smallest sales unit of a medical device changes, the medical device registrant or filer shall make modifications to the UDI database to update the data prior to product marketing. Where the device identifier of the smallest sales unit of a medical device changes, data shall be uploaded to the UDI database as a newly added device identifier.

III. Relevant requirements

(1) Medical device registrants or filers shall earnestly fulfill their primary responsibilities. They are encouraged to establish and improve a traceability system based on UDI, and properly carry out product recall, tracking and traceability, adverse event monitoring, and other relevant work. Where the regulatory class of a product changes due to adjustment of the *Classification Catalogue for Medical Devices,* medical device registrants or filers shall implement UDI in accordance with the requirements of the adjusted regulatory class. For medical devices eligible for UDI exemption in accordance with the *Announcement of the National Medical Products Administration on the Implementation of Unique Device Identification for Medical Devices in Specific Circumstances* (No. 15, 2026), medical device registrants or filers may be exempted from UDI implementation in accordance with the requirements of the *Rules for Unique Device Identification System.*

(2) Medical device distributors shall actively apply UDI in business activities, and properly conduct code-based warehousing and delivery. Enterprises shall upload relevant information to the National Healthcare Security Information Platform in accordance with the relevant provisions of healthcare security authorities to realize traceability of products in the circulation sector.

(3) Medical institutions shall actively apply UDI in clinical practices such as clinical use, adverse event reporting, payment and charging, and settlement and reimbursement, keep full-process code-based records, and realize traceability of products in the clinical sector.

(4) Issuing agencies shall formulate UDI coding standards and guidelines for their own agencies, guide medical device registrants or filers in UDI creation and assignment, and verify the readability of UDI coded in accordance with their standards in the circulation and use sectors.

(5) Provincial drug regulatory authorities shall strengthen training and guidance on UDI implementation, upgrade the medical device registration/filing system to meet the needs of implementation work, organize medical device registrants or filers within their jurisdictions to

标识的单独变化不属于备案/注册变更范畴。

（三）唯一标识数据库提交

2027年6月1日起生产的全部第二类医疗器械（包括体外诊断试剂）和全部第一类体外诊断试剂，2029年6月1日起生产的全部第一类医疗器械，在其上市销售前，医疗器械注册人、备案人应当按照相关标准或者规范要求将最小销售单元、更高级别包装的产品标识和相关数据上传至医疗器械唯一标识数据库，确保数据真实、准确、完整、可追溯。对于已在国家医保局医保医用耗材、医保体外诊断试剂等医保分类与代码数据库中维护信息的医疗器械，要在医疗器械唯一标识数据库中补充完善医保医用耗材、医保体外诊断试剂等医保分类与代码字段，同时在医保医用耗材、医保体外诊断试剂等医保分类与代码数据库维护中完善医疗器械唯一标识相关信息，并确认与医疗器械唯一标识数据库数据的一致性。

当医疗器械最小销售单元产品标识相关数据发生变化时，医疗器械注册人、备案人应当在产品上市销售前，在医疗器械唯一标识数据库中进行变更，实现数据更新。医疗器械最小销售单元产品标识变化时，应当按照新增产品标识在医疗器械唯一标识数据库上传数据。

三、有关要求

（一）医疗器械注册人、备案人要切实落实主体责任，鼓励基于唯一标识建立健全追溯体系，做好产品召回、追踪追溯、不良事件监测等有关工作。对于因《医疗器械分类目录》调整导致产品管理类别发生变化的情况，医疗器械注册人、备案人应当按照调整后管理类别的要求实施唯一标识。对于符合《国家药监局关于特定情形实施医疗器械唯一标识有关事项的公告》（2026年第15号）中免于实施唯一标识的医疗器械，医疗器械注册人、备案人可免于按照《医疗器械唯一标识系统规则》的要求实施唯一标识。

（二）医疗器械经营企业要在经营活动中积极应用唯一标识，做好带码入库、出库。企业按照医保部门有关规定，将相关信息上传至国家医保信息平台，实现产品在流通环节可追溯。

（三）医疗机构要在临床使用、不良事件报告、支付收费、结算报销等临床实践中积极应用唯一标识，做好全程带码记录，实现产品在临床环节可追溯。

（四）发码机构要制定针对本机构的唯一标识编制标准及指南，指导医疗器械注册人、备案人开展唯一标识创建、赋码工作，并验证按照其标准编制的唯一标识在流通、使用环节可识读性。

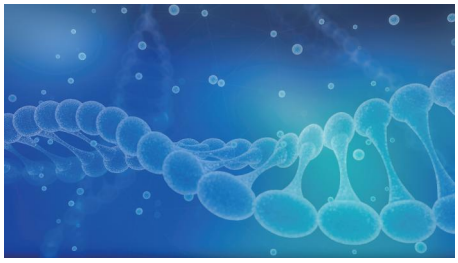
carry out product coding, data upload and maintenance as required, strengthen coordination with health and healthcare security authorities within their jurisdictions, and promote tripartite coordination among healthcare, medical insurance, and drugs.

(6) Provincial health authorities shall guide medical institutions within their jurisdictions to actively apply UDI and strengthen standardized management of medical devices in clinical use.

(7) Provincial healthcare security authorities shall strengthen the associated application of healthcare security classification and codes for medical consumables, in vitro diagnostic reagents, and other items with UDI, and promote transparency and intelligence of catalog access, payment management, volume-based procurement, and other work.

It is hereby announced.

National Medical Products Administration
National Health Commission
National Healthcare Security Administration
March 4, 2026
(March 13, 2026)



（五）省级药品监督管理部门要加强唯一标识工作的培训指导，结合实施工作推进需求做好医疗器械注册/备案系统改造，组织行政区域内医疗器械注册人、备案人按要求开展产品赋码、数据上传和维护工作，加强与行政区域内卫生健康、医保部门协同，推动三医联动。

（六）省级卫生健康部门要指导行政区域内医疗机构积极应用唯一标识，加强医疗器械在临床使用中的规范管理。

（七）省级医保部门要加强医保医用耗材、医保体外诊断试剂等医保分类与代码和医疗器械唯一标识的关联使用，推动目录准入、支付管理、带量招标等的透明化、智能化。

特此公告。

国家药监局 国家卫生健康委 国家医保局
2026年3月4日
（2026-03-13）

Notes:
- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
- For e-copy of the Newsletter, please visit http://www.ccfdie.org

备 注：
- Newsletter中所有中文信息均摘自报刊及网络。英文均系中文翻译。如有出入，请以中文为准。
- 电子版Newsletter阅览请登录网站http://www.ccfdie.org

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