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法律法规简报

Legal Update

2025-05



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1. 国家药监局发布《医疗器械网络销售质量管理规范》 2025.04.28 NMPA Publishes Good Practice for Online Sales of Medical Devices

为加强医疗器械网络销售监督管理,规范医疗器械网络销售质量管理,保障公众用械安全有效,促进医疗器械产业发展,根据相关法规规章规定,国家药监局制定了《医疗器械网络销售质量管理规范》(下称“《规范》”),自2025年10月1日起施行。

In order to strengthen the supervision and administration of online sales of medical devices, standardize the quality management of online sales of medical devices, ensure the safe and effective use of medical devices by the public, and promote the development of the medical device industry, the National Medical Products Administration (NMPA) has formulated the *Good Practice for Online Sales of Medical Devices* (“*Good Practice*”) in accordance with the relevant laws and regulations, which will come into effect on October 1st, 2025.

《规范》共四章 50 条,重点对医疗器械网络销售和电子商务平台经营者管理提供了指引。一是明确基本原则。从事医疗器械网络销售和为医疗器械网络交易提供电子商务平台服务,应当坚持诚实守信,确保网络销售医疗器械信息的真实、准确、完整和可追溯,采取有效措施防控网络销售医疗器械质量安全风险。二是规范网络销售行为。规定从事网络销售的医疗器械企业要展示必要经营信息、产品信息,加强质量管理体系建设。三是强化电商平台管理。指导电子商务平台经营者在医疗器械网络交易服务的全过程中采取有效的质量控制措施,全面保障网络销售医疗器械产品的质量和可追溯。

Good Practice consists of four chapters and 50 articles, focusing on providing guidance to the online sales of medical devices and e-commerce platform operators. Firstly, it clarifies the basic principles. Those who engage in the online sales of medical devices and provide e-commerce platform services for online medical device transactions shall adhere to honesty and integrity and ensure the authenticity, accuracy, completeness, and traceability of information related to the online sales of medical devices. Effective measures shall be taken to control the quality and safety risks associated with the online sales of medical devices. Secondly, it regulates online sales behavior. It is stipulated that medical device enterprises engaged in online sales should display necessary business information, product information, and strengthen the construction of quality management system. Thirdly, it strengthens the management of e-commerce platform. It guides e-commerce platform operators to take effective quality control measures in the whole process of medical device network trading services, to comprehensively ensure the quality safety and traceability of online sales of medical devices.



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(Source: <https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20250428184452126.html>
<https://www.nmpa.gov.cn/yaowen/ypjgyw/ylqxyw/20250429165714165.html>)

2. 全国人大常委会表决通过《民营经济促进法》 2025.04.30 NPC Standing Committee Passes Private Sector Promotion Law

第十四届全国人民代表大会常务委员会第十五次会议审议通过《中华人民共和国民营经济促进法》（下称“《民营经济促进法》”），自 5 月 20 日起施行。

At the 15th Session of the Standing Committee of the 14th National People's Congress (NPC), the *Private Sector Promotion Law of the People's Republic of China* (“*Private Sector Promotion Law*”) is deliberated and passed. The *Private Sector Promotion Law* has taken effect on May 20th, 2025.

《民营经济促进法》共九章 78 条，围绕公平竞争、投资融资促进、科技创新、规范经营、服务保障、权益保护等方面建立完善相关制度机制，持续优化稳定、公平、透明、可预期的民营经济发展环境。《民营经济促进法》积极回应民营企业关切，作出针对性制度安排，确保企业公平参与市场竞争方面、平等使用生产要素方面、同等受到法律保护方面。

The *Private Sector Promotion Law* consists of nine chapters and 78 articles, establishing and improving relevant institutional mechanisms in the areas of fair competition, investment and financing promotion, scientific and technological innovation, standardization of business operations, service guarantee and protection of rights and interests, with a view to continuously optimizing a stable, fair, transparent and predictable environment for the development of private sector. The *Private Sector Promotion Law* actively responds to the concern of private sector and makes targeted institutional arrangements to ensure that enterprises participate fairly in market competition, use factors of production on an equal basis, and are equally protected by the law.

(Source: https://www.gov.cn/yaowen/liebiao/202504/content_7021914.htm)

3. 仲裁法修订草案等五部法律草案征求意见 2025.04.30 Five Draft Laws Including the Arbitration Law Draft Seek Comments

第十四届全国人民代表大会常务委员会第十五次会议对《中华人民共和国仲裁法（修订草案）（二次审议稿）》（下称“《仲裁法二次审议稿》”）、



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《中华人民共和国生态环境法典（草案）》等五部法律草案进行了审议，现对外公布全文，面向社会征求意见，征求期限为 45 日。

The 15th Session of the Standing Committee of the 14th National People's Congress (NPC) has deliberated five draft laws, including the *Arbitration Law of the People's Republic of China (Second Draft Revision for Review)* (the “*Arbitration Law Second Draft*”), *Ecological and Environmental Code of the People's Republic of China (Draft)*, with the full text of these draft laws announced to solicit public comments for a term of 45 days.

《仲裁法二次审议稿》拟主要修改以下几个方面内容：一是加强仲裁监督，提高仲裁公信力；二是完善仲裁委员会制度，优化担任仲裁员的条件；三是完善涉外仲裁制度，加强仲裁对外交流合作；四是完善法院支持仲裁的相关制度，明确仲裁委员会提交的当事人对财产、行为、证据的保全申请，人民法院应当依法及时处理。

Main revisions to the *Arbitration Law Second Draft* include following aspects: (1) strengthening the supervision of arbitration and enhancing the credibility of arbitration; (2) improving the arbitration committee system and optimizing the conditions for serving as an arbitrator; (3) improving the system of arbitration involving foreign countries and strengthening the foreign communications and cooperation of arbitration; and (4) improving the system of the courts in support of arbitration by making it clear that the party's application for the preservation of property, acts and evidence submitted by the arbitration committee shall be timely dealt with by the People's Courts in accordance with the law.

(Source: <http://www.npc.gov.cn/flcaw/>
http://www.npc.gov.cn/npc//c2/c30834/202504/t20250425_444888.html)

4. 自然资源部就规范矿业权登记管理相关规定征求意见 2025.05.16 MNR Seeks Comments on Provisions to Regulate the Administrative Measures of Registration of Mining Rights

为贯彻落实新修订的《矿产资源法》，规范矿业权登记行为，优化完善矿产资源勘查开采许可管理制度，促进矿产资源合理开发利用，自然资源部起草了《自然资源部关于印发〈矿业权登记管理办法〉的通知（征求意见稿）》《自然资源部关于矿产资源勘查开采许可管理有关事项的通知（征求意见稿）》，现向社会公开征求意见，截至 2025 年 6 月 5 日。

In order to implement the newly revised *Mineral Resources Law*, regulate the registration of mining rights, optimize and improve the permission and management



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system of mineral resources exploration and exploitation, and promote the rational development and utilization of mineral resources, the Ministry of Natural Resources (MNR) has drafted the *Circular of the Ministry of Natural Resources on the Issuance of Administrative Measures for Mining Rights Registration (Draft)*, the *Circular of the Ministry of Natural Resources on Matters Relating to the Administration of Permission for Mineral Resources Exploration and Exploitation (Draft)*, which are now open to the public for comments until June 5th, 2025.

《自然资源部关于印发〈矿业权登记管理办法〉的通知（征求意见稿）》贯彻落实《民法典》《矿产资源法》关于矿业权登记的要求，借鉴不动产登记的做法，强化物权保护；做好新旧制度的有效衔接并简化登记程序和要件，明确各类登记的适用情形和办理的具体要件资料，方便实际操作。《矿业权登记管理办法》以附件形式发布，主要是矿业权登记的具体操作规定。

The *Circular of the Ministry of Natural Resources on the Issuance of Administrative Measures for Mining Rights Registration (Draft)* implements the requirements of the *Civil Code* and the *Mineral Resources Law* on the registration of mining rights, takes example by the practice of real estate registration to strengthen the protection of property rights; effectively connects the old and new systems and simplifies the registration procedures and requirements, clarifying the applicable circumstances and specific information for various types of registration to facilitate practical operation. The *Administrative Measures for Mining Rights Registration* is issued in the form of attachment, which is mainly about specific operational provisions for the registration of mining rights.

《自然资源部关于矿产资源勘查开采许可管理有关事项的通知（征求意见稿）》统筹设计勘查开采许可和矿业权登记管理制度，推进勘查开采许可和矿业权登记同步申请、同步审批，精简审批环节，共享审批要件；明确勘查方案、开采方案和矿区生态修复方案编制评审管理要求，重新设计勘查、采矿许可申请书等附件内容。

The *Circular of the Ministry of Natural Resources on Matters Relating to the Administration of Permission for Mineral Resources Exploration and Exploitation (Draft)* coordinates and designs the management system of permission for exploration and exploitation and mining right registration, promotes the synchronization of the application and approval of permission for exploration and exploitation and mining right registration, streamlines the approval links and shares approval requirements; specifies exploration program, exploitation program and assessment management requirements of ecological restoration of the mining area program, and redesign the application and other attachments for exploration and mining permission.



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(Source: https://gi.mnr.gov.cn/202505/t20250521_2884607.html)

5. 海关总署发布公告加强洋山特殊综合保税区有关商品管理 2025.05.19 **GACC Issues Announcement to Strengthen the Management of Goods in Yangshan Free Trade Zone**

为加强洋山特殊综合保税区涉及实施关税配额管理, 贸易救济措施, 中止关税减让义务、加征关税措施, 为征收报复性关税而实施加征关税措施(以下统称四类措施)等商品的管理, 海关总署于 2025 年 5 月 19 日发布海关总署公告 2025 年第 90 号(下称“《公告》”), 自 2025 年 6 月 10 日起实施。

In order to strengthen the management of goods in Yangshan Free Trade Zone involving the implementation of tariff quota management, trade remedy measures, suspension of tariff concession obligations and tariff increase measures, tariff increase measures for the purpose of collecting retaliatory tariffs (“four categories of measures”), the General Administration of Customs of the People’s Republic of China (GACC) issued the *GACC Announcement No.90 of 2025* on May 19th, 2025 (the “*Announcement*”), which will come into effect on June 10th, 2025.

根据《公告》洋山特殊综合保税区企业开展保税业务涉及从境外进口四类措施商品的, 应设立专用账册。境外进口的四类措施商品不进入专用账册的, 不得保税; 洋山特殊综合保税区企业通过专用账册进出境的货物, 不适用径予放行模式; 洋山特殊综合保税区企业通过专用账册与其他海关特殊监管区域、保税监管场所企业之间流转保税货物的, 核注清单监管方式应填报“1200”, 运输方式填报“9”, 其他填制规范按照《保税核注清单填制规范》规定执行。According to the *Announcement*, enterprises in the Yangshan Free Trade Zone carrying out bonded business involving the import of goods subject to four categories of measures from overseas are required to establish dedicated accounts. Imported goods subject to four categories not recorded in the dedicated accounts, shall not be bonded. Goods entering or exiting the Yangshan Free Trade Zone through these accounts will not be eligible for the direct release model. Enterprises in the Yangshan Free Trade Zone transfer bonded goods to or from enterprises in other special customs supervision zones or bonded supervision areas via dedicated accounts, the supervision mode on the verification list should be filled in as “1200” and the mode of transportation as “9”. Other filling specifications shall comply with the *Filling Specifications for Bonded Verification List*.

(Source: <http://gdfs.customs.gov.cn/customs/302249/2480148/6527099/index.html>)



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