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法律法规简报

Legal Update

2025-03

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1. 上期所扩大合格境外投资者参与商品期货、期权交易范围 2025.02.28

SHFE Expands the Investment Scope of Qualified Foreign Investors in Commodity Futures and Options

为便于合格境外机构投资者和人民币合格境外机构投资者（下称“合格境外投资者”）进一步参与上海期货交易所（下称“上期所”）商品期货、期权的交易，上期所发布《关于扩大合格境外投资者参与商品期货、期权交易范围的公告》（下称“《公告》”）和《关于做好扩大合格境外投资者参与商品期货、期权交易范围有关事项的通知》。

In order to facilitate the further participation of Qualified Foreign Institutional Investors and RMB Qualified Foreign Institutional Investors (collectively referred to as Qualified Foreign Investors, QFI) in the trading of commodity futures and options of Shanghai Futures Exchange (SHFE), SHFE has recently issued the *Circular on Expanding the Investment Scope of Qualified Foreign Investors in Commodity Futures and Options* (the "*Circular*") and the *Notice on Expanding the Investment Scope of Qualified Foreign Investors in Commodity Futures and Options*.

根据《公告》，经中国证监会同意，自 2025 年 3 月 4 日交易（即 3 月 3 日晚夜盘）起，上期所将扩大合格境外投资者可交易品种范围，新增开放不锈钢、燃料油、纸浆期货合约和白银、螺纹钢期权合约。

According to the *Circular*, with the approval of the China Securities Regulatory Commission, starting from March 4th, 2025 (i.e., from the continuous trading session on March 3rd, 2025), the SHFE will expand the investment scope of QFI, to include the following commodity futures and options contracts: (1) Stainless Steel, Fuel Oil, and Woodpulp futures contracts; and (2) Silver, Steel Rebar options contracts.

(Source:
https://www.shfe.com.cn/publicnotice/notice/202502/t20250228_824658.html
https://www.shfe.com.cn/publicnotice/notice/202502/t20250228_824655.html)

2. 国家药监局修订医疗器械临床试验项目检查要点及判定原则 2025.03.12

NMPA Revises Inspection Points and Determination Principles for Medical Device Clinical Trial Projects

为规范医疗器械临床试验检查工作，统一检查范围和判定标准，提高医疗器械临床试验项目检查质量，根据《医疗器械监督管理条例》、《医疗器械注册与备案管理办法》和《医疗器械临床试验质量管理规范》等规定，国家药监局组织修订《医疗器械临床试验项目检查要点及判定原则》（下称“《检查要点及判定原则》”）。

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In order to standardize the inspection of medical device clinical trials, unify the scope of inspection and determination standards, and improve the quality of inspection of medical device clinical trials, according to the *Regulations on the Supervision and Administration of Medical Devices*, *Administrative Measures for the Registration and Record-filing of Medical Devices* and *Good Clinical Practice for Medical Device Trials*, the National Medical Products Administration revised the *Inspection Points and Determination Principles for Medical Device Clinical Trial Projects* (the "*Inspection Points and Determination Principles*").

《检查要点及判定原则》提出统一判定原则，体现医疗器械和体外诊断试剂质量管理理念的一致性；分述检查要点，体现了两个领域各自特点。一是明确检查要点。将现场检查要点分为临床试验条件与合规性、受试者权益保障、临床试验方案、临床试验实施过程、临床试验记录与报告、试验器械管理等板块。二是完善检查内容。根据法规调整和监管实际，细化临床试验实施过程、临床试验数据溯源、体外诊断试剂样本溯源等检查内容。三是优化真实性问题判定原则。将判定结果细化为"真实性问题、严重不符合要求问题、规范性问题、符合要求"四种情形。

The *Inspection Points and Determination Principles* provides a unified approach to determination principles, ensuring consistency in quality management concepts for medical devices and in vitro diagnostic reagents; separately elaborates the inspection points, considering the unique characteristics of two fields. First is to clarify the key points of the inspection. On-site inspection is divided into clinical trial conditions and compliance, protection of the rights and interests of the subjects, clinical trial program, clinical trial implementation process, clinical trial records and reports, test equipment management and others. Second is to improve the inspection content. According to the adjustment of regulations and regulatory practice, the inspection contents of clinical trial implementation process, clinical trial data traceability, in vitro diagnostic reagent sample traceability, etc. have been refined. Third is to optimize the principle of determining authenticity problems. The judgment results are refined into four scenarios: authenticity problem, serious non-compliance problem, standardization problem, and compliance.

(Source: https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/20250312095404175.html)

3. 自然资源部就《矿产资源法实施条例》征求意见 2024.03.17

MNR Seeks Comments on the Implementation Regulations of the Mineral Resources Law

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为进一步健全完善以《矿产资源法》为核心的矿产资源法律法规体系，自然资源部起草了《中华人民共和国矿产资源法实施条例（征求意见稿）》（下称"《实施条例》"）。为了增强立法的公开性和透明度，提高立法质量，现征求社会各界意见，意见反馈截止于 4 月 15 日。

In order to further improve the mineral resources laws and regulations system centered on the *Mineral Resources Law*, the Ministry of Natural Resources has drafted the *Implementation Regulations of the Mineral Resources Law of the People's Republic of China (Draft for Comments)* (the "*Implementation Regulations*"). In order to enhance the openness and transparency of the legislation and to improve the quality of the legislation, the *Implementation Regulations* is now soliciting opinions from the public until April 15th.

《实施条例》共八章七十五条，对新《矿产资源法》进行了全面细化。主要内容包括：（一）完善地质调查制度；（二）完善矿产资源规划制度；（三）完善矿业权管理制度；（四）规范勘查开采管理；（五）完善矿业用地管理；（六）健全矿产资源储量管理制度；（七）健全矿区生态修复制度；（八）完善矿产资源储备和应急管理制度。

The *Implementation Regulations*, consisting of eight chapters and 75 articles, provides comprehensive details for the new *Mineral Resources Law* and mainly includes: (1) improving the geological survey system; (2) enhancing the mineral resources planning system; (3) refining the management system for mineral rights; (4) standardizing exploration and mining management; (5) improving the land use management for the mining activities; (6) strengthening the management system for mineral resources reserves; (7) enhancing the ecological restoration system for mining areas; and (8) improving the system for mineral resource reserves and emergency management.

(Source: https://gi.mnr.gov.cn/202503/t20250317_2882016.html)

4. 国家药监局调整优化进口医疗器械产品在中国境内企业生产事项 2024.03.18

NMPA Adjusts and Optimizes Matters Concerning the Production of Imported Medical Device Products by Enterprises within China

2020 年 9 月，《国家药监局关于进口医疗器械产品在中国境内企业生产有关事项的公告》（下称"《公告》"）发布实施，为持续深化医疗器械监管改革，促进医疗器械产业高质量发展，国家药监局就《公告》作出进一步调整和优化。

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In September 2020, the *Announcement of the National Medical Products Administration on Matters Concerning the Production of Imported Medical Device Products by Enterprises within China* (the "*Announcement*") was released and implemented. In order to continue deepening the reform of the regulation of medical devices and to promote the high-quality development of the medical device industry, the National Medical Products Administration has made further adjustments and optimizations to the *Announcement*.

《公告》调整内容包括：（一）调整适用范围。"外商投资企业"由进口医疗器械注册人设立，调整至"可以是进口医疗器械注册人设立的企业，或者与进口医疗器械注册人具有同一实际控制人的企业"且实际控制人应当符合《公司法》相关定义和规定；（二）调整注册申报要求；（三）注册体系核查要求优化；（四）支持创新产品转产。

Adjustments to the *Announcement* include: (1) adjusting the scope of application. "Foreign-invested enterprises" shall be established by the registrant of imported medical devices, adjusted to "can either be enterprises established by the registrant of the imported medical devices, or enterprises under the same actual controller as the registrant of the imported medical devices. The actual controller should meet the relevant definitions and requirements set forth in the Company Law; (2) adjusting the registration declaration requirements; (3) optimizing the registration system verification requirements; (4) supporting the innovative products to production.

(Source: https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/20250318152218159.html)

5. 最高法明确涉外国国家豁免民事案件相关程序事项 2025.03.27

SPC Clarifies Procedural Matters for Civil Cases Involving Foreign State Immunity

为正确审理涉外国国家豁免民事案件，保护当事人合法权益，维护国家主权平等，根据《中华人民共和国外国国家豁免法》（下称"《外国国家豁免法》"）《中华人民共和国民事诉讼法》的相关规定，最高人民法院发布《关于涉外国国家豁免民事案件相关程序事项的通知》（下称"《通知》"）。

In order to properly adjudicate civil cases involving foreign state immunity, protect the legitimate rights and interests of the parties concerned and safeguard the sovereign equality, the Supreme People's Court issued the *Circular on Procedural Matters Relating to Civil Cases Involving Foreign State Immunity* (the "*Circular*") in accordance with the relevant provisions of the *Law of the People's Republic of China*

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on Foreign State Immunity (the "*Foreign State Immunity Law*") and the *Civil Procedure Law of the People's Republic of China*.

《通知》共八条，规定了涉外国国家豁免民事案件的受理、集中管辖、送达、对管辖豁免的审查、外交部证明文件的取得等程序性内容。《通知》对于确保各地法院在收到涉外国国家的起诉时，准确把握《外国国家豁免法》的精神要义，依法做好相关案件的受理审查工作具有重要指导意义。

The *Circular*, consisting of eight articles, stipulates procedural requirements for the acceptance, centralized jurisdiction, service, review of jurisdictional immunity, and obtaining certification documents from the Ministry of Foreign Affairs in civil cases involving foreign state immunity. The *Circular* is of great significance as a guide to ensure that local courts accurately grasp the spirit of the *Foreign State Immunity Law* when lawsuits involving foreign States are received and accept and examine the relevant cases in accordance with the law.

(Source: https://ipc.court.gov.cn/zh-cn/news/view-4094.html)

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