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法律法规简报 2022-06-29

Legal Update 2022-06-29

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一、两部门启动数据安全认证工作 2022.06.09

Two Authorities Launch Data Security Management Certification

近日，国家市场监督管理总局、国家互联网信息办公室联合发布《数据安全认证实施规则》（下称《规则》），并同步发出公告，对相关工作进行部署。



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The State Administration for Market Regulation ("SAMR") and the Cyberspace Administration of China ("CAC") have jointly released the *Implementation Rules for Data Security Management Certification* (the "Rules"), with an announcement simultaneously distributed to arrange for relevant work.

根据公告，两部门决定开展数据安全认证工作，鼓励网络运营者通过认证方式规范网络数据处理活动，加强网络数据安全保护。从事数据安全认证活动的认证机构应当依法设立，并按照《规则》实施认证。《规则》规定了对网络运营者开展网络数据收集、存储、使用、加工、传输、提供、公开等处理活动进行认证的基本原则和要求。数据安全认证的认证模式为“技术验证+现场审核+获证后监督”。认证机构根据认证委托资料、技术验证报告、现场审核报告和其他相关资料信息进行综合评价，作出认证决定。

According to the announcement, the two authorities decide to launch data security management certification and all network operators are encouraged to regulate their online data processing activities and strengthen their online data security protection by way of certification. Certification institutions engaged in data security management certification shall be legally established and shall carry out certification work pursuant to the *Rules*. The *Rules* specify the basic principles and requirements governing the certification of various online data processing activities conducted by network operators, covering online data collection, storage, use, processing, transmission, provision, and disclosure. Data security management certification shall adopt the mode of "technical verification plus onsite inspection plus post-certification supervision". The certification institutions shall carry out a comprehensive evaluation based on the certification entrustment materials, technical verification reports, on-site inspection reports and other relevant materials and information, before making the decision on certification.

(Source: https://gkml.samr.gov.cn/nsjg/rzjgs/202206/t20220609_347615.html)

二、国家药监局拟加强医疗器械生产经营分级监管

2022.06.06



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NMPA to Tighten Graded Regulation of Medical Devices Manufacturing and Operation

日前, 国家药品监督管理局修订形成《关于加强医疗器械生产经营分级监管工作的意见(征求意见稿)》(下称《征求意见稿》), 现向社会征求意见, 意见反馈截止于 6 月 19 日。

Recently, the National Medical Products Administration ("NMPA") has developed upon revision the *Opinions on Tightening Graded Regulation of the Manufacturing and Operation of Medical Devices (Draft for Comment)* (the "*Draft for Comment*"), to solicit opinions from the public by June 19, 2022.

《征求意见稿》主要修改如下: 一是将分级监管规定修改为指导意见。二是精简调整重点监管目录。三是科学强化监督管理。四是引入信用监管理念。其中, 《征求意见稿》明确对质量管理体系运行状况差、有严重不良信用记录注册人备案人、受托生产企业实施四级监管, 对上年度存在行政处罚或者存在不良信用记录的经营企业实施三级监管; 对长期以来质量管理状态和监管信用状况较好的企业, 可以酌情下调监管级别。

The main revisions of the *Draft for Comment* include the following: the first is to change the "regulations on grade regulation" as "guiding opinions"; the second is to streamline and adjust the catalogue of regulatory priorities; the third is to scientifically step up supervision and management efforts; and the fourth is to introduce the concept of credit-based regulation. Among them, the *Draft for Comment* clarifies that four-grade supervision will be exercised on the registrants, record-filing applicants, and entrusted manufactures that are found to have a poor quality management system or serious bad credit records; and that three-grade supervision will be exercised on enterprises that have been given administrative penalties or had bad credit records in the previous year; and that the grade of supervision can be lessened as appropriate for enterprises with good quality management status and good regulatory credit records for a long term.

(Source: <https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjylqx/20220602160159175.html>)



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三、央行发文支持外贸新业态跨境人民币结算 2022.06.21

PBC to Support Cross-border RMB Settlement in New Forms of Foreign Trade

近日，中国人民银行发布《关于支持外贸新业态跨境人民币结算的通知》（下称《通知》），自 7 月 21 日起施行。

The People's Bank of China ("PBC") has recently released the *Circular on Supporting Cross-border RMB Settlement in New Forms of Foreign Trade* (the "*Circular*") for implementation from July 21, 2022.

《通知》主要内容包括：一是加大对外贸新业态的支持力度，完善跨境电商等外贸新业态跨境人民币业务相关政策。二是将支付机构跨境业务办理范围由货物贸易、服务贸易拓宽至全部经常项下。三是明确银行、支付机构等相关业务主体展业和备案要求。四是明确业务真实性审核、反洗钱、反恐怖融资、反逃税以及数据报送等要求，压实银行与支付机构展业责任，防控业务风险。其中，《通知》规定，与支付机构合作的境内银行应具备 3 年以上开展跨境人民币结算业务的经验，满足备付金银行相关要求，具备审核支付机构跨境人民币结算业务真实性、合法性的能力，具备适应支付机构跨境人民币结算业务特点的反洗钱、反恐怖融资、反逃税系统处理能力。

The *Circular* mainly involves: (1) increasing the support for new forms of foreign trade and improving relevant policies for cross-border renminbi ("RMB") settlement in new forms of foreign trade, such as cross-border e-commerce; (2) expanding the cross-border business scope of payment institutions from trade in goods and trade in services to current account; (3) clarifying the business operation and record-filing requirements for banks, payment institutions and other relevant entities; (4) specifying the requirements on business authenticity review, prevention of money laundering, counter terrorist financing and tax evasion, and data reporting, reinforcing the business responsibilities of banks and payment institutions, and preventing business risks. Among others, the *Circular* stipulates that the domestic banks cooperating with payment institutions shall have more than three years of experience in carrying out cross-border RMB settlement business, meet the relevant requirements for excess



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reserves, have the capability to review the authenticity and legality of the cross-border RMB settlement business conducted by payment institutions, and have the capability to systematically prevent and deal with money laundering, terrorist financing, and tax evasion, which is adaptive to the cross-border RMB settlement business characteristics.

(Source: <http://www.pbc.gov.cn/tiaofasi/144941/3581332/4581686/index.html>)

四、全国人民代表大会常务委员会关于修改《中华人民共和国反垄断法》的决定

2022.06.24

Decision of the Standing Committee of the National People's Congress on Amending the Anti-Monopoly Law of the People's Republic of China

近日，第十三届全国人民代表大会常务委员会第三十五次会议通过《关于修改〈中华人民共和国反垄断法〉的决定》（下称《决定》）。《决定》自 2022 年 8 月 1 日起施行。

The 35th Session of the Standing Committee of the 13th National People's Congress ("NPC") has recently adopted the *Decision on Amending Anti-Monopoly Law of the People's Republic of China* (the "*Decision*"). The *Decision* will come into effect from August 1, 2022.

《决定》共二十五条，进一步完善反垄断相关制度规则。为更好地规范平台经济领域竞争秩序，《决定》新增了两个条款。一是经营者不得利用数据和算法、技术、资本优势以及平台规则等从事本法禁止的垄断行为。二是具有市场支配地位的经营者不得利用数据和算法、技术以及平台规则等从事前款规定的滥用市场支配地位的行为。而在垄断协议方面，一是完善了纵向垄断协议的认定规则，对于经营者与交易相对人达成的纵向垄断协议，经营者能够证明不具有排除、限制竞争效果的，不予禁止。二是增加了垄断协议安全港规则，对于经营者与交易相对人达成的纵向垄断协议，经营者的市场份额低于规定标准并符合其他相关条件的，不予禁止。三是增加规定，经营者不得组织其他经营者达成垄断协议或者为其他经营者达成垄断协议提供实质性帮助。



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The *Decision*, consisting of 25 articles, further improves the relevant anti-monopoly rules and systems. To better regulate the competition order in the platform economy sector, the *Decision* adds two provisions. Firstly, business operators shall not use data, algorithms, technologies, capital advantages, and platform rules to engage in any monopolistic practices prohibited herein. Secondly, business operators with the market dominance shall not abuse their market dominance as prescribed in the preceding paragraph by making use of data, algorithms, technologies, and platform rules. Regarding the monopoly agreement, firstly, the *Decision* perfects the rules for identifying vertical monopoly agreement, specifying that a vertical monopoly agreement by and between the business operator and its transaction counterparty will not be prohibited if the business operator can prove that it does not have the effect of excluding or limiting competition. Secondly, the *Decision* adds a safe harbor rule for monopoly agreement, clarifying that a vertical monopoly agreement by and between the business operator and its transaction counterparty will not be prohibited if the market share of the business operator is lower than a stipulated level and it can meet other relevant conditions. Thirdly, a new article is added, reading "a business operator must not organize other business operators to enter into a monopoly agreement or provide substantive assistance to other business operators in entering into a monopoly agreement."

(Source: <http://www.npc.gov.cn/npc/c30834/202206/e42c256faf7049449cdfaabf374a3595.shtml>)

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