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法律法规简报 2021-10-28

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NPC Standing Committee Seeks Comments on Anti-Monopoly Law (Draft Amendments)

一、商务部发布《“十四五”利用外资发展规划》 2021.10.22

MOFCOM Issues Development Plan for Use of Foreign Investment during the 14th Five-year Plan Period



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近日，商务部编制《“十四五”利用外资发展规划》（下称《规划》）。

The Ministry of Commerce (“MOFCOM”) has recently formulated the *Development Plan for Use of Foreign Investment during the 14th Five-year Plan Period* (the “Plan”).

根据《规划》，“十四五”时期，利用外资规模位居世界前列，利用外资大国地位稳固，利用外资结构持续优化，与对外投资、对外贸易、促进消费的联动作用进一步加强，为促进国内经济大循环、联接国内国际双循环发挥更加积极作用。

According to the *Plan*, during the 14th Five-year Plan period, China's scale for the use of foreign investment will reach the top level in the world, its status as a strong power in the use of foreign investment will remain stable, its structure for the use of foreign investment will keep optimizing, and the linkage effect of boosting overseas investment, foreign trade and consumption will be further strengthened. Therefore, the use of foreign investment will play a more positive role in driving domestic circulation with domestic and international circulations reinforcing each other.

其中，外商投资准入范围将进一步扩大。据此，《规划》明确了推进更高水平对外开放、优化利用外资结构、强化开放平台功能等举措。《规划》提出，要放宽重点领域准入门槛，推动放宽外商投资法律、运输等行业业务范围、人员资质等要求。同时，稳妥推进银行、证券、保险、基金、期货等金融领域开放。

Among others, the scope of market access for foreign investment will be further expanded. The *Plan* specifies multiple measures, including advancing a higher level of opening up, optimizing the structure for use of foreign investment, and strengthening the functions of open platforms. Meanwhile, the *Plan* calls for relaxing the market entry in some key areas, expanding the business scope for foreign investors, such as law, transport and other industries, and lifting some restrictions related to qualifications; steadily promoting the opening up of banking, securities, insurance, funds, futures and other financial sectors.



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(Source: <http://www.mofcom.gov.cn/article/zwgk/gkzcfb/202110/20211003210174.shtml>)

二、国家药监局明确实施医疗器械注册与备案管理办法有关事项 2021.09.30

NMPA Clarifies Relevant Matters Concerning the Implementation of Administrative Measures for the Registration and Record-filing of Medical Devices

近日，国家药品监督管理局发布《关于实施〈医疗器械注册与备案管理办法〉〈体外诊断试剂注册与备案管理办法〉有关事项的通告》（下称《通告》）。

The National Medical Products Administration ("NMPA") has recently issued the *Circular on Relevant Matters Concerning the Implementation of the Administrative Measures for the Registration and Record-filing of Medical Devices and the Administrative Measures for the Registration and Record-filing of In Vitro Diagnostic Reagents* (the "Circular").

《通告》称，《医疗器械注册与备案管理办法》和《体外诊断试剂注册与备案管理办法》（统称《办法》）已发布，自 10 月 1 日起施行。为做好《办法》实施工作，现明确《办法》实施前已受理注册申请项目的处理、补正材料涉及的检验报告、新的强制性标准实施之日前受理注册申请项目的审查等七类事项。

The *Circular* makes clear that both the *Administrative Measures for the Registration and Record-filing of Medical Devices* and the *Administrative Measures for the Registration and Record-filing of In Vitro Diagnostic Reagents* (collectively, the "Measures") have been released and shall come into effect from October 1, 2021. To effectively implement the *Measures*, relevant matters in seven aspects are hereby clarified, such as the handling of the projects of which the applications have been accepted before the *Measures* take effect, the inspection reports involved in supplementary materials, and the review of the projects of which the applications have been accepted before the new mandatory standards take effect.



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其中,《通告》规定,《办法》实施前已受理但尚未作出审批决定的注册申请项目,药品监管部门按照原规定继续审评审批,符合上市条件的,发给医疗器械注册证。延续注册的注册证有效期起始日执行《办法》第八十四条规定。

Among others, the *Circular* specifies that if the application of a project has been accepted before the *Measures* take effect, but an approval decision has not been made, the medical products regulator may continue the review and approval processes pursuant the previous provisions, and if the conditions for marketing are met, a registration certificate for medical product will be issued. The effective date of a registration certificate for renewing registration shall be subject to the Article 84 of the *Measures*.

(Source: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210929171254177.html>)

三、国家发改委就《市场准入负面清单(2021年版)》征求意见 2021.10.09

NDRC Seeks Comments on the Negative List for Market Access (2021 Version)

日前,国家发展和改革委员会公布《市场准入负面清单(2021年版公开征求意见稿)》(下称《征求意见稿》),现向社会征求意见,征求时间截止于10月14日。

The National Development and Reform Commission ("NDRC") has recently issued the *Negative List for Market Access (2021 Version) (Draft for Comment)* (the "*Draft for Comment*") to solicit public opinions by October 14, 2021.

《征求意见稿》列有禁止准入事项6项,许可准入事项111项,共计117项,相比2020年版减少6项。对负面清单以外的行业、领域、业务等,各类市场主体皆可依法平等进入。其中,《征求意见稿》禁止违规开展金融相关经营活动。非金融机构、不从事金融活动的企业,在注册名称和经营范围中原则上不得使用“融资租赁”、“商业保理”、“小额贷款”、“金融”、“资产管理”、“网贷”、



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“网络借贷”、“P2P”、“互联网保险”、“支付”、“外汇（汇兑、结售汇、货币兑换）”、“基金管理”等与金融相关的字样。

The *Draft for Comment* proposes a total of 117 items, including six items of prohibited access and 111 items of approved access, six items less than previous year. All kinds of market players may enjoy equal access to industries, fields, business outside the List in accordance with the law. Among others, the *Draft for Comment* prohibits any illegal business activity related to finance. A non-financial institution or an enterprise not engaged in any financial activity shall not use in its registered name or business scope any finance-related word, such as "financial leasing", "commercial factoring", "small loan", "finance", "asset management", "financial management", "online loans", "Internet lending", "P2P", "Internet insurance", "payment", "foreign exchange (exchange, exchange settlement, currency exchange)" and "fund management".

(Source: https://hd.ndrc.gov.cn/yjzx/yjzx_add.jsp?SiteId=371)

四、全国人大常委会就反垄断法修正草案征求意见

2021.10.25

NPC Standing Committee Seeks Comments on Anti-Monopoly Law (Draft Amendments)

近日，第十三届全国人民代表大会常务委员会第三十一次会议就《中华人民共和国反垄断法（修正草案）》面向社会征求意见，征求均截止于11月21日。

The 31st session of the Standing Committee of the 13th National People's Congress has deliberated the *Anti-Monopoly Law of the People's Republic of China (Draft Amendments)*, the full texts of which have been released to the public for comments by November 21, 2021.

《反垄断法（修正草案）》主要作出以下四个方面修改：一是明确了竞争政策的基础地位和公平竞争审查制度的法律地位。二是进一步完善反垄断相关制度规则。三是进一步加强对反垄断执法的保障。四是完善法律责任，加大处罚力度。



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其中，明确规定具有市场支配地位的经营者利用数据和算法、技术以及平台规则等设置障碍，对其他经营者进行不合理限制的，属于滥用市场支配地位的行为。

Among others, the *Anti-Monopoly Law (Draft Amendments)* proposes the following revisions: (1) clarifying the status of the competition policy as a basic policy and the legal status of fair competition review system; (2) further perfecting the relevant anti-monopoly rules and systems; (3) further enhancing the guarantee measures for anti-monopoly law enforcement; (4) improving the provisions on legal liability and imposing stricter penalties. It also specifies that setting an obstacle using any data, algorithm, technology, platform rules or otherwise by a business operator with a dominant market position to impose any unreasonable restriction on another business operator shall be deemed an abuse of dominant market position.

(Source: <http://www.npc.gov.cn/flcaw/userIndex.html?lid=ff8081817ca258e9017ca5fa67290806>)

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