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法律法规简报 2022-03-31

Legal Update 2022-03-31

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NMPA to Regulate the Record-filing of Class I Medical Devices

一、市场监管总局公布《医疗器械生产监督管理办法》等 2022.03.23

SAMR Releases Measures for the Supervision and Administration of Medical Device Production and Others

近日，国家市场监督管理总局发布《医疗器械生产监督管理办法》和《医疗器械经营监督管理办法》（统称《办法》），均自5月1日起施行。



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The State Administration for Market Regulation ("SAMR") has recently released the *Measures for the Supervision and Administration of Medical Device Production* and the *Measures for the Supervision and Administration of the Business Operations of Medical Devices* (collectively, the "*Measures*"), both with effect from May 1, 2022.

《办法》全面落实医疗器械注册人备案人制度，优化行政许可办理流程，强化监督检查措施，完善监督检查手段，夯实企业主体责任，并加大对违法行为的处罚力度。其中，关于夯实企业主体责任，《办法》建立了医疗器械生产报告制度，规定生产产品品种报告、生产动态报告、生产条件变化报告和质量管理体系运行情况自查年度报告等要求。

The *Measures* fully implement the system of medical device registrants and record-filing persons, optimize the administrative licensing process, strengthen supervision and inspection approaches, improve supervision and inspection methods, consolidate the main responsibilities of the enterprises, and impose greater penalties for illegal acts. Among others, in order to consolidate the main responsibilities of the enterprises, the *Measures* establish a medical device production reporting system, which stipulates the requirements on product variety report, production progress report, production condition change report and annual report on self-inspection of quality management system.

同时，《办法》优化了许可备案流程，对医疗器械注册人制度下有关经营许可、备案等要求进行调整，取消许可时提交营业执照及有关证明文件要求，压缩核查审批时限，明确免于提交申请资料和免于经营备案的具体情形，并对同时申请许可和备案的，简化材料提交等程序要求。

Meanwhile, the *Measures* call for optimizing the license filing process, adjusting the requirements for business licenses and record-filing under the medical device registrant system, handing in business licenses and relevant certification documents in case of license cancellation, shortening the time limit for verification and approval, and clarifying the circumstances for exemption from submitting application materials and making business record-filing; in terms of application for registration and record-filing at the same time, materials submission and other procedures are simplified.



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(Source: https://gkml.samr.gov.cn/nsjg/fgs/202203/t20220322_340682.html)

二、两部门印发《市场准入负面清单（2022 年版）》 2022.03.25

Negative List for Market Access (2022 Version) Issued by Two Authorities

日前，国家发展和改革委员会、商务部共同发出《市场准入负面清单（2022 年版）》（下称《清单》），并同步下发通知，对相关工作进行部署。《清单》自发布之日起施行。

The National Development and Reform Commission ("NDRC") and the Ministry of Commerce ("MOFCOM") have jointly issued the *Negative List for Market Access (2022 Version)* (the "*List*"), with a circular being simultaneously distributed to arrange for relevant work. The *List* shall become effective from the date of issuance.

《清单》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。市场准入负面清单分为禁止和许可两类事项，其中对禁止准入事项，市场主体不得进入，行政机关不予审批、核准，不得办理有关手续。对市场准入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。通知则从严格落实“全国一张清单”管理要求、切实履行政府监管责任、建立违背市场准入负面清单案例归集和通报制度等五个方面，对有关工作提出要求。

The *List* provides a total of 117 matters, six matters less than the 2020 version, of which there are six prohibited access matters and 111 approved access matters. The *List* is divided into two categories, namely, prohibited matters and approved matters. For prohibited access matters, market players shall not engage in them, and administrative organs shall not examine or approve them or handle the relevant formalities. For industries, areas and businesses beyond the *List*, all kinds of market players may enjoy equal access pursuant to the law. The circular specifies the requirements for relevant work in five aspects, such as strictly implementing the administrative requirement of "one list nationwide", earnestly fulfilling the regulatory duties of the governments, and establishing a system for collecting and reporting cases involving violation of the negative list for market access.



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(Source:

https://www.ndrc.gov.cn/xwdt/tzgg/202203/t20220325_1320233.html?code=&state=123)

三、最高法出台反不正当竞争法司法解释 2022.03.17

SPC Releases Judicial Interpretations on Anti-Unfair Competition Law

近日，最高人民法院下发《关于适用〈中华人民共和国反不正当竞争法〉若干问题的解释》（下称《解释》），自 3 月 20 日起施行。

The Supreme People's Court ("SPC") has recently released the *Interpretations on Relevant Issues Concerning the Application of the Anti-Unfair Competition Law of the People's Republic of China* (the "*Interpretations*").

《解释》共 29 条，根据修订后的反不正当竞争法，重点对反不正当竞争法第二条、仿冒混淆、虚假宣传、网络不正当竞争行为等问题作出细化规定。其中，针对仿冒混淆问题，《解释》用 11 个条文，重点从以下三个方面对反不正当竞争法第六条“仿冒混淆”的规定进行了细化：一是《解释》第四条明确“有一定影响的”标识的含义和认定考量因素。二是《解释》第七条明确：属于商标法禁用禁注范围的标志也不能获得反不正当竞争法的保护。三是参照《市场主体登记管理条例》第二条的规定，细化了名称可以受到保护的 market 主体的范围。

The *Interpretations*, consisting of 29 articles and based on the revised *Anti-Unfair Competition Law*, mainly detail Article 2 of the *Anti-Unfair Competition Law*, and address such issues as counterfeit and confusion, false publicity, and unfair competition behaviors online. Among others, regarding the "counterfeit and confusion", the *Interpretations* offer 11 articles to provide detailed interpretations on the "counterfeit and confusion", as specified in Article 6 of the *Anti-Unfair Competition Law*, from the following three perspectives. Firstly, Article 4 of the *Interpretations* clarifies the definition of the mark with "influence to a certain extent", and the factors to be considered when identifying such mark. Secondly, Article 7 of the *Interpretations*



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stipulates that if a mark is among those prohibited from use and registration under the *Trademark Law*, it will not be protected under the *Anti-Unfair Competition Law*. Thirdly, by following Article 2 of the *Administrative Regulations on the Registration of Market Entities*, the *Interpretations* refine the scope of the market entities whose names can be protected.

(Source: <https://www.court.gov.cn/fabu-xiangqing-351291.html>)

四、国家药监局拟规范第一类医疗器械备案事项 2022.03.03

NMPA to Regulate the Record-filing of Class I Medical Devices

日前，国家药品监督管理局发出《关于第一类医疗器械备案有关事项的公告（征求意见稿）》（下称《征求意见稿》），现公开征求意见，意见反馈截止于 3 月 31 日。

Recently, the National Medical Products Administration ("NMPA") has issued the *Announcement on Matters Concerning the Record-filing of Class I Medical Devices (Draft for Comment)* (the "*Draft for Comment*") for public comments by March 31, 2022.

根据《征求意见稿》，境内第一类医疗器械备案，备案人向设区的市级负责药品监督管理的部门提交备案资料。进口第一类医疗器械备案，备案人向国家药监局提交备案资料。《征求意见稿》明确，备案人应当按要求编制进行备案医疗器械的产品技术要求。备案人提交符合《征求意见稿》附件 1 规定的备案资料后即完成备案。

According to the *Draft for Comment*, for the record-filing of domestic Class I medical devices, the applicant shall submit record-filing materials to the authority responsible for drug supervision and administration at the city level with districts. For the record-filing of imported Class I medical devices, the applicant shall submit record-filing materials to the NMPA. The *Draft for Comment* clarifies that the applicant shall prepare the product technical requirements for filing medical devices as required. The record-



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filing will be completed after the applicant submits the record-filing materials conforming to the requirements set forth in Appendix 1 of the *Draft for Comment*.

对备案的医疗器械, 备案部门应当自备案之日起 5 个工作日内, 公布《第一类医疗器械备案信息表》或《第一类体外诊断试剂备案信息表》中登载的有关信息。《征求意见稿》还要求, 备案部门应当按照第一类医疗器械备案操作规范开展备案工作。

For the filed medical devices, the record-filing authority shall, within five working days from the date of record-filing, make public the relevant information stated in the Form of Class I Medical Device Record-filing Information or the Form of Class I In Vitro Diagnostic Reagent Record-Filing Information. The *Draft for Comment* also requires that the record-filing authorities should carry out the record-filing work in accordance with record-filing practices for Class I medical devices.

(Source: <https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjylqx/20220302135737184.html>)

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