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法律法规简报 2023-05-31

Legal Update 2023-05-31

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一、国家药监局就《药品标准管理办法》再次征求意见 2023.05.06

NMPA Seeks Comments Once Again on the Administrative Measures for Medical Product Standards

近日，国家药品监督管理局起草了《药品标准管理办法（征求意见稿）》（下称《征求意见稿》），现向社会再次征意，意见反馈截至 6 月 5 日。



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Recently, the National Medical Products Administration (NMPA) has released the *Administrative Measures for Medical Product Standards (Draft for Comment)* (the “Draft”), which is open for the public comments once again until June 5, 2023.

《征求意见稿》具有以下特点：一是明确了药品标准体系构成及标准间的关系；二是明确药品标准管理工作各方的职责；三是强化持有人主体责任落实；四是建立鼓励社会各方参与药品标准制修订的工作机制；五是建立药品标准快速制修订通道；六是关于新版《中国药典》颁布后药品标准适用性评估；七是解决的其他问题。其中，《征求意见稿》规定持有人应当随着社会发展与科技进步以及对产品认知的不断提高，持续提升和完善药品注册标准；新版药典颁布后，持有人应当主动对药品执行标准与新版药典的适用性进行评估，并根据评估结果按照药品上市后变更相关规定进行办理，持续提升药品标准。

Highlights of the *Draft* include the following: firstly, it clarifies the framework of the medical product standard system and the relationship between various standards. Secondly, it defines the duties of all parties involved in medical product standard management. Thirdly, it emphasizes the importance of marketing authorization holders (MAHs) fulfilment their responsibilities. Fourthly, it establishes a mechanism for all parties to participate in the formulation and revision of medical product standards. Fifthly, it establishes a fast-track mechanism for formulation and revision of medical products standards. Sixthly, it evaluates the applicability of medical product standards after the introduction of the new version of the *Chinese Pharmacopoeia*. Finally, it addresses other issues. Notably, the *Draft* emphasizes that MAHs should continue to improve medical product registration standards in alignment with social development, technological progress, and product awareness. They should also evaluate the applicability of the new version of *Pharmacopoeia*, follow the relevant regulations on post-marketing changes of medical products based on the evaluation results, and continuously improve medical product standards.

(Source: <https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20230505175001137.html>)

二、市场监管总局就行业协会反垄断指南征求意见 2023.05.16



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SAMR Seeks Comments on Anti-monopoly Guide to Industry Associations

近日，国家市场监督管理总局起草了《关于行业协会的反垄断指南（征求意见稿）》（下称《征求意见稿》），现向社会征求意见，意见反馈截至 6 月 15 日。

The State Administration for Market Regulation (SAMR) has recently drafted the *Anti-monopoly Guide to Industry Associations (Draft for Comment)* (the “*Draft*”) to solicit public opinions by June 15, 2023.

《征求意见稿》提出，行业协会不得违反《中华人民共和国反垄断法（2022 年修正）》第二十一条的规定，组织本行业的经营者从事垄断协议行为。前款所称从事，包括垄断协议的达成和实施。《征求意见稿》进一步对横向垄断协议，纵向垄断协议，组织达成垄断协议的情形，组织实施垄断协议的情形，滥用行政权力排除、限制竞争等加以明确，并鼓励和支持行业协会充分发挥自律职能，加强自身反垄断合规建设，采取行业规则、公约以及市场自治规则等方式，指导、帮助会员建立健全反垄断合规管理制度，尽早识别、防范垄断风险。

The *Draft* stipulates that industry associations shall not violate Article 21 of the *Anti-Monopoly Law of the People's Republic of China (Revised in 2022)* by organizing the business operators in their corresponding industries to conduct the acts of monopoly agreement. The term “conduct” in the preceding paragraph shall include both the conclusion and the implementation of a monopoly agreement. Furthermore, the *Draft* sets forth detailed provisions on horizontal monopoly agreement, vertical monopoly agreement, the circumstances where entities are organized to conclude monopoly agreement, the circumstances where entities are organized to implement monopoly agreement, abuse of administrative power to exclude and restrict competition, among others. It also encourages and supports industry associations to give full play to their self-discipline functions, strengthen their own anti-monopoly compliance, adopt industry rules, conventions, and market autonomy rules, guide and help their members establish sound anti-monopoly compliance management systems, and identify and prevent monopoly risks as early as possible.



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(Source:

https://www.samr.gov.cn/hd/zjdc/art/2023/art_dc8a945808794ad2b15de191f657d645.html)

三、海关总署修改《进出口商品抽查检验管理办法》等三部规章 2023.05.23

GAC Revises Three Rules Including Administrative Measures for the Spot-check and Inspection of Import and Export Commodities

近日，海关总署发出《海关总署关于修改部分规章的决定》（下称《决定》），自 7 月 1 日起施行。

The General Administration of Customs (GAC) has recently issued the *Decision of the General Administration of Customs on Revising Some Rules* (the “Decision”), with effect from July 1, 2023.

《决定》对《中华人民共和国海关对保税仓库及所存货物的管理规定（2018 年修订）》、《中华人民共和国海关对出口监管仓库及所存货物的管理办法（2018 年 11 月修订）》和《进出口商品抽查检验管理办法（2018 年修订）》（下称《办法》）等三部规章进行修改。其中，《决定》将原《办法》第二条中的“《商检法》规定”修改为“《商检法》及其实施条例规定”。同时，删除第四条中的“确定、调整和公布实施抽查检验的进出口商品的种类”；将第五条中的“预警通告”修改为“风险预警”；删除第十条中的“每年”；删除第二十四条。《决定》还对《办法》第十一条、第十二条和第十六条作出修改。

The *Decision* revises three rules, namely, the *Administrative Provisions of the Customs of the People's Republic of China on Bonded Warehouses and the Goods Stored Therein (Revised in 2018)*, the *Administrative Measures of the Customs of the People's Republic of China for Export Supervised Warehouses and the Goods Stored Therein (Revised in November 2018)*, and the *Administrative Measures for the Spot-check and Inspection of Import and Export Commodities (Revised in 2018)* (the “Measures”). Among others, in Article 2 of the previous *Measures*, the *Decision* revises the



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expression “as stipulated in the *Commodity Inspection Law*” into “as stipulated in the *Commodity Inspection Law* and its implementing regulations”. Meanwhile, the expression “and define, adjust and publish the varieties of import and export commodities subject to spot-check and inspection” in Article 4 is deleted; “warning notice” in Article 5 is changed into “risk warning”; “each year” in Article 10 is deleted; and Article 24 is removed. The *Decision* also proposes revisions to Articles 11, 12, and 16.

(Source: <http://www.customs.gov.cn/customs/302249/2480148/5043425/index.html>)

四、国务院公布修订后《商用密码管理条例》 2023.05.25

Revised Regulations on the Administration of Commercial Cryptography Issued by State Council

近日，国务院下发《商用密码管理条例（2023 年修订）》（下称《条例》），自 7 月 1 日起施行。

The State Council has recently distributed the *Regulations on the Administration of Commercial Cryptography (Revised in 2023)* (the “*Regulations*”), with effect from July 1, 2023.

《条例》重点规定了以下内容：一是完善商用密码管理体制；二是促进商用密码科技创新与标准化建设；三是健全商用密码检测认证体系；四是加强电子认证服务使用密码和电子政务电子认证服务活动管理；五是规范商用密码进出口管理；六是促进商用密码应用。其中，《条例》根据《密码法》关于商用密码进出口的规定和国家出口管制、两用物项进出口管理制度，明确商用密码进口许可和出口管制实行清单管理，并规定了审批程序。同时，《条例》鼓励公民、法人和其他组织依法使用商用密码保护网络与信息安全，支持网络产品和服务使用商用密码提升安全性。明确关键信息基础设施的商用密码使用要求和国家安全审查要求。



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The *Regulations* mainly involve: (1) improving the management system for commercial cryptography; (2) promoting the technological innovation and standardization of commercial cryptography; (3) establishing a sound testing and certification system for commercial cryptography; (4) strengthening the use of cryptography in electronic authentication services and the management of e-government electronic authentication service activities; (5) standardizing import and export management for commercial cryptography; and (6) promoting the application of commercial cryptography. Among others, the *Regulations* adopt list-based management of the import license and export control for commercial cryptography in accordance with the provisions on the import and export of commercial cryptography in the *Cryptography Law*, as well as the national export control and the administrative rules for dual-use item import and export, and clarify the approval procedures. The *Regulations* encourage the legal use of commercial cryptography by citizens, legal persons and other organizations to protect network and information security, and support the use of commercial cryptography for network products and services to enhance security. The requirements for the use of commercial cryptography for critical information infrastructure and the relevant requirements for national security review are also provided.

(Source: http://www.gov.cn/zhengce/content/202305/content_6875927.htm)

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