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法律法规简报 2022-07-31

Legal Update 2022-07-31

目录

Contents

◆ [国家网信办公布《数据出境安全评估办法》](#)

Measures for the Security Assessment of Outbound Data Transfers Released by CAC

◆ [国家药监局公布《疫苗生产流通管理规定》](#)

NMPA Issues the Administrative Provisions on Vaccine Production and Distribution

◆ [国务院印发 2022 年度立法工作计划](#)

State Council Issues 2022 Legislative Plan

◆ [市场监管总局：试点委托开展部分经营者集中案件反垄断审查](#)

SAMR to Authorize Pilot Provincial Regulators to Conduct Anti-monopoly Review of Some Cases of Concentration of Undertakings

一、国家网信办公布《数据出境安全评估办法》

2022.07.07

Measures for the Security Assessment of Outbound Data Transfers Released by CAC

近日，国家互联网信息办公室发布《数据出境安全评估办法》（下称《办法》），自9月1日起施行。



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The Cyberspace Administration of China ("CAC") has recently released the *Measures for the Security Assessment of Outbound Data Transfers* (the "*Measures*"), with effect from September 1, 2022.

《办法》规定了应当申报数据出境安全评估的情形，包括数据处理器向境外提供重要数据、关键信息基础设施运营者和处理 100 万人以上个人信息的数据处理器向境外提供个人信息、自上年 1 月 1 日起累计向境外提供 10 万人个人信息或者 1 万人敏感个人信息的数据处理器向境外提供个人信息以及其他情形。《办法》提出数据出境安全评估的具体要求，规定数据处理器在申报数据出境安全评估前应当开展数据出境风险自评估并明确重点评估事项。规定数据处理器在与境外接收方订立的法律文件中明确约定数据安全保护责任义务，在数据出境安全评估有效期内发生影响数据出境安全的情形应当重新申报评估。此外还明确了数据出境安全评估程序、监督管理制度等。

The *Measures* specify the circumstances where application for security assessment is required, including outbound transfer of important data by a data processor, outbound transfer of personal information by a critical information infrastructure operator or a personal information processor who has processed the personal information of more than 1,000,000 persons, outbound transfer of personal information by a personal information processor who has made outbound transfers of the personal information of 100,000 persons cumulatively or the sensitive personal information of 10,000 persons cumulatively since 1 January of the previous year, and other circumstances. The *Measures* propose the basic requirements for security assessment of outbound data transfers. The *Measures* also require the data processor to conduct a self-assessment of the risks in the outbound data transfer before applying for the security assessment of an outbound data transfer, and identify the following matters. The data processor is required to have the data security protection responsibilities and obligations clearly stipulated in the legal document executed with the overseas recipient and to reapply for the security assessment where the security of outbound data transfer may be affected. In addition, the procedures for the security assessment and the supervisory system are specified.

(Source: http://www.cac.gov.cn/2022-07/07/c_1658811536396503.htm)



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二、国家药监局公布《疫苗生产流通管理规定》 2022.07.08

NMPA Issues the Administrative Provisions on Vaccine Production and Distribution

近日，国家药品监督管理局发出《疫苗生产流通管理规定》（下称《规定》），自发布之日起施行。

Recently, the National Medical Products Administration ("NMPA") has issued the *Administrative Provisions on Vaccine Production and Distribution* (the "*Provisions*"), with effect on the date of issuance.

《规定》提出，国家对疫苗生产实施严格准入制度，严格控制新开办疫苗生产企业。新开办疫苗生产企业，除符合疫苗生产企业开办条件外，还应当符合国家疫苗行业主管部门的相关政策。同时，《规定》强调，国家对疫苗实行上市许可持有人制度。持有人应当按照采购合同的约定，向疾病预防控制机构销售疫苗。持有人应当按照规定，建立真实、准确、完整的销售记录，销售记录应当至少包含产品通用名称、批准文号、批号、规格、有效期、购货单位、销售数量、单价、金额、销售日期和持有人信息等，委托储存、运输的，还应当包括受托储存、运输企业信息，并保存至疫苗有效期满后不少于 5 年备查。

The *Provisions* state that, China implements a strict access system for vaccine production and rigorously controls the newly established vaccine production enterprises. Newly established vaccine production enterprises, in addition to meeting the conditions for the establishment of vaccine production enterprises, should also comply with relevant policies of the vaccine industry authority of the State. In addition, the *Provisions* emphasize that the State implements a marketing authorization holder (MAH) system for vaccines, specifying that a MAH holder should sell vaccines to disease prevention and control institutions under the terms of the purchase contracts, and that the MAH holder should establish truthful, accurate and complete sales records as required. The sales records should include, among others, the general name of the product, approval number, batch number, specification, validity period, purchaser, sales



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quantity, unit price, amount, sales date, and the information of the MAH holder; and in case of entrusted storage and transportation, the information about the storage and transportation enterprises that are entrusted should be included as well, and such above information should be retained for not less than five years after the expiration of the vaccine validity period for future reference.

(Source: <https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20220708185734126.html>)

三、国务院印发 2022 年度立法工作计划 2022.07.14

State Council Issues 2022 Legislative Plan

近日，国务院办公厅发布《国务院 2022 年度立法工作计划》（下称《计划》）。

The General Office of the State Council has issued the *2022 Legislative Plan of the State Council* (the "Plan").

《计划》包括拟提请全国人大常委会审议的法律案（16 件）、拟制定修订的行政法规（16 件）以及拟完成的其他立法项目。其中，根据《计划》，要围绕全面深化改革开放、推动经济高质量发展，提请全国人大常委会审议关税法草案、增值税法草案、金融稳定法草案、铁路法修订草案。制定城市公共交通条例、国务院关于反走私综合治理的若干规定，修订商用密码管理条例、专利法实施细则。预备提请全国人大常委会审议国家发展规划法草案、消费税法草案、电信法草案、反不正当竞争法修订草案、会计法修订草案、银行业监督管理法修订草案、中国人民银行法修订草案、商业银行法修订草案、反洗钱法修订草案、保险法修订草案、计量法修订草案、对外贸易法修订草案、仲裁法修订草案。

The *Plan* includes 16 draft laws to be submitted to the Standing Committee of the National People's Congress ("NPC") for deliberation, 16 administrative regulations to be formulated or revised, and other legislative projects to be completed. According to the *Plan*, the legislative work shall aim to thoroughly deepen the reform and opening up,



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and drive the high-quality economic development. The *draft tariff law*, the *draft value-added tax law*, the *draft financial stability law*, and the *revised draft of railway law* will be submitted to the NPC Standing Committee for deliberation. The *urban public transport regulations* and the *several provisions of the State Council on comprehensive anti-smuggling governance* will be formulated, and the *regulations on the administration of commercial cryptography*, and the *implementing rules of the patent law* will be revised. Preparations have been made for requesting the NPC Standing Committee to review the *draft national development planning law*, the *draft consumption tax law*, the *draft telecommunications law* and the *revised drafts of the anti-unfair competition law*, *accounting law*, *banking regulation law*, *law on People's Bank of China*, *commercial bank law*, *anti-money laundering law*, *insurance law*, *metrology law*, *foreign trade law* and *arbitration law*.

(Source: http://www.gov.cn/zhengce/content/2022-07/14/content_5700974.htm)

四、市场监管总局：试点委托开展部分经营者集中案件反垄断审查 2022.07.15

SAMR to Authorize Pilot Provincial Regulators to Conduct Anti-monopoly Review of Some Cases of Concentration of Undertakings

日前，国家市场监督管理总局发布《关于试点委托开展部分经营者集中案件反垄断审查的公告》（下称《公告》）。

Recently, the State Administration for Market Regulation ("SAMR") has issued the *Announcement on Authorizing the Conducting of Anti-monopoly Review of Some Cases of Concentration of Undertakings on a Pilot Basis* (the "*Announcement*").

《公告》拟于 8 月 1 日起试点委托北京市、上海市、广东省、重庆市、陕西省市场监督管理局开展部分适用经营者集中简易程序的案件反垄断审查工作。

《公告》明确，试点期间，市场监管总局将部分简易案件委托试点省级市场监管部门负责审查。市场监管总局统一受理经营者集中申报并在试点省级市场监管部门审查意见基础上作出审查决定。试点省级市场监管部门按照市场监管总局统一的经营集中工作规则，进行材料审核、立案审查，并在规定时限内完成审查，



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将审查报告和审查建议报市场监管总局。总局作出审查决定后，试点省级市场监管部门将审查决定送达申报人。试点期限至 2025 年 7 月 31 日。

Under the *Announcement*, the SAMR intends to authorize market regulatory authorities of Beijing, Shanghai, Guangdong, Chongqing, and Shaanxi to carry out anti-monopoly review of some cases in which the simplified procedures for concentration of undertakings apply, on a pilot basis, from August 1, 2022. The *Announcement* clarifies that, during the pilot period, the SAMR will authorize the pilot provincial market regulators to conduct review of some simple cases, and it will accept the prior notifications of concentration of undertakings in a uniform manner and make review decisions based on the review opinions of the pilot provincial market regulators. The pilot provincial market regulators shall, in accordance with the uniform rules of the SAMR for the concentration of undertakings, conduct review of materials and case-filing review, and complete the reviews within the specified time limit, and then submit the review reports and review recommendations to the SAMR. After the SAMR makes the review decisions, the pilot provincial market regulators will deliver such decisions to the applicants. The pilot period ends on July 31, 2025.

(Source: https://gkml.samr.gov.cn/nsjg/flides/202207/t20220715_348645.html)

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