

China Newsletter | Q2 2023/Issue No. 57



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Antitrust

SAMR Seeks Comments on Anti-Monopoly Compliance Guidelines for Concentrations of Undertakings

市场监管总局对《经营者集中反垄断合规指引》征求意见

On June 19, 2023, the State Administration for Market Regulation (SAMR) issued the *Draft of Antitrust Compliance Guidelines for Undertakings Concentrations* (Draft), soliciting public comments until July 3, 2023.

The highlights of the Draft are set forth below:

- The Draft clarifies through citing a specific case that the acquired shareholding percentage alone may not be decisive in determining the acquisition of control. Other factors should be taken into consideration, especially the voting rights weighted in senior management appointment, financial budgets, business plans, etc. It specifies that even minority equity investments may trigger the notification obligation.
- The Draft clarifies through citing a specific case that a step-by-step transaction (i.e. the steps are interrelated) may trigger a notification obligation before the first step is taken even if it does not immediately trigger an acquisition of control.
- The Draft encourages undertakings to establish a sound merger-control compliance system based on business scale, management mode, frequency of concentration, existing compliance system, etc. The SAMR clarifies that when it investigates undertakings' practices of unlawful implementation of concentrations, it will take into account the establishment and implementation of anti-monopoly compliance systems when determining penalties.

Compliance

China to Strengthen Supervision Over Online Cosmetics Operations

国家药监局公布《化妆品网络经营监督管理办法》

On March 31, 2023, China's National Medical Products Administration (NMPA) released the *Measures on the Supervision and Administration of Online Cosmetics Operations* (the Measures), which took effect

Sept. 1, 2023. Through the Measures, NMPA will further regulate the online cosmetics market and clarify each stakeholder's responsibilities. Following are some key takeaways about the Measures:

1. Applicability:

The Measures apply to e-commerce cosmetics operators within the territory of China, including e-commerce cosmetics platform operators (platform operators), cosmetics platform operators (i.e., cosmetics sellers), and other e-commerce operators who operate cosmetics through self-built websites and other online services.

Notably, Article 34 of the Measures clarifies that cross-border e-commerce retailers who engage in importing cosmetics are not subject to the Measures but should abide by the relevant national regulations on the supervision of cross-border e-commerce retail of imported commodities.

2. Obligations of Platform Operators:

Platform operators are responsible for managing cosmetics sellers on the platforms, including carrying out real-name registrations and daily inspections; stopping and reporting non-compliant manners; reporting quality and safety issues to relevant authorities, etc. In addition, platform operators must set up cosmetics quality and safety management systems or establish full-time/part-time positions to oversee the safety and quality of cosmetics.

Notably, the Measures also require that platform operators take immediate action to control and stop illegal business operations by cosmetics sellers on the platforms, including acting to delete or block the weblinks for illegal products or illegal sellers. Platform operators must also report serious safety and quality issues to local NMPA for further investigation. Furthermore, each quarter platform operators should report to the local NMPA illegal business operations found on the platform and the corresponding measures taken against such illegal activities.

3. Obligations of the Cosmetics Sellers:

Cosmetics sellers must conduct purchase inspections, disclose the cosmetics labels (which information should be consistent with that provided on the filing or registration certificate of such cosmetics), take risk-control measures, and conduct product recall, etc.

China releases newly amended Anti-Espionage Law

新修订《反间谍法》正式颁布

On April 26, 2023, China passed the amended Counter-Espionage Law (the "New Law"), which took effect July 1, 2023. The New Law expands the definition of espionage activities, explicitly including acts of turning towards espionage organizations and their agents. Further, the New Law prohibits stealing, spying, purchasing, or illegally providing the documents, data, materials, or items related to "national security and interests," as state secrets and intelligence already are afforded these protections. In addition, the New Law specifically identifies cyberattacks against state agencies, secret-related entities and critical information infrastructure (CII) as an additional category of espionage activity. Nonetheless, the New Law applies to espionage activities targeting a third country, which activities occurred within the territory of the People's Republic of China (PRC) or where the PRC citizens, organizations or other conditions are utilized, and which would eventually endanger PRC national security.

The New Law also bolsters investigation and enforcement measures. Regarding individuals suspected of espionage, authorities may check the belongings of those whose identity is unknown or are suspected of espionage, carry out the search and inspection of persons, objects and places relating to suspected espionage, and prevent overseas personnel linked to espionage from entering or leaving the country. Moreover, if the state security agencies discover risks such as online content or cyberattacks involving espionage activities, they will notify the relevant competent departments, and such departments will order the telecommunication operators or internet service providers to repair loopholes, strengthen network protection, shut down or stop the transmission of information, suspend related services, remove related applications, close related websites, and save the records. In emergencies, where national security is immediately endangered, state security departments will directly order relevant entities to repair loopholes, stop the transmission, and suspend the service.

Additionally, the New Law expands the application of administrative penalties by fining for minor violations involving espionage activities, adding that fines can be imposed for minor violations involving espionage; increasing the types of penalties, such as interviews, notification of criticism, suspension or revocation of licenses; and clarifying the legal responsibility for helping others to commit espionage.

The Ministry of Ecology and Environment released the Measures for Ecological and Environmental Administrative Penalties

生态环境部公布《生态环境行政处罚办法》

On May 8, 2023, the Ministry of Ecology and Environment (MEE) released the *Measures for Ecological and Environmental Administrative Penalties* (the “2023 Measures”), with effect from July 1, 2023, and which replaced the *2010 Measures for Environmental Administrative Penalties* (the “2010 Measures”). The 2023 Measures implement new requirements stipulated under the 2021 amended superior Law on Administrative Penalties and further regulate the exercise of discretion in administrative penalties for ecological and environmental violations. Highlights of the 2023 Measures include:

1. Scope of Application

The 2010 Measures excluded nuclear and radiation pollution and subjected such pollution to separate rules. The 2023 Measures remove this exclusion.

2. Types of Administrative Penalties

To be consistent with the Law on Administrative Penalties, the 2023 Measures add new penalty types including circulation of criticism, confiscation of illegal income, confiscation of illegal property, reduction of qualification grade, prohibition of application for administrative licenses within a certain time period, restriction on production and business activities, suspension of production, remediation, and demolition within time limit.

3. Improvement on the Discretion of Penalties

The 2023 Measures modify the discretionary powers to impose administrative penalties in accordance with the Law on Administrative Penalties, adding provisions on circumstances where penalties are to be lightened or mitigated and further updating circumstances where no penalties are to be imposed.

SAMR to Further Regulate Advertising Censorship for Drugs, Medical Devices, Dietary Supplements, and Foods for Special Medical Purposes

市场监管总局拟规范“三品一械”广告审查管理工作

On May 29, 2023, the State Administration for Market Regulation (SAMR) released the amended draft of *Administrative Measures for Censoring Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purposes* (the “Draft Measures”) for public comment. The public comment period closed June 28. The revision aims to enhance enforcement of advertising regulations, facilitate business operations, and improve the advertising censorship system. Highlights of the Draft Measures include:

1. A new provision requiring that advertisements for food other than dietary supplements neither claim to have health care functions, nor express or imply that they have certain health care functions by publicizing the effects of certain ingredients.
2. A requirement that advertisements not contain theoretical references, expressions of opinion beyond the instructions, or references to literature, research reports, experimental proofs and other content.
3. A stipulation that advertisements for drugs, medical devices, dietary supplements and foods for special medical purposes (i) must not be published on mass media targeting minors; (ii) must not be published in disguise in webcasts in the form of health and wellness knowledge, etc., or (iii) must not be endorsed or recommended by a spokesman in the webcast.

Data Privacy & Cybersecurity

TC260 Issues Implementation Guidelines for Data Security Risk Assessments

信安标委编发网络数据安全风险评估实施指引

On May 26, 2023, the National Information Security Standardization Technical Committee (TC260) released the *Practical Guide to Cybersecurity Standards - Implementation Guidelines for Risk Assessment of Network Data Security* (“Guidelines”) to provide guidance for data security self-assessment conducted by data processors as well as assessment conducted by third party institutions. Regulatory agencies may also use the Guidelines as reference when they organize data security assessment on data processors.

The Guidelines provide a security risk assessment procedure for content, proposing that (i) the risk assessment may be conducted as to data security management, data processing activities, data securing technology, protection of personal information and background information (please see the chart below for details); and (ii) a complete risk assessment consists of five stages: preparation, survey, risk identification, analysis, and assessment.

Data security management	Data processing activities	Data securing technology	Protection of personal information	Background information
System and procedures	Data collection	Cyber protection	Basic principles	Information of data processor
Organizations	Data storage	Authentication and access control	Consent	Business information system
Classified and graded system	Data transfer	Monitoring and prewarning	Obligations	Status of data asset
Staff management	Data processing and transmission	Data masking	Rights	Status of data processing
Outsourcing management	Data provision	Data leakage prevention	Complaints and reports	Security measures
Threat and error management	Data disclosure	API security	Processing of personal information	
Development and operation	Data deletion	Backup and restore	Protection of sensitive personal information	
Security of cloud data		Safety audit	Large online platform	

Content framework of risk assessment

CAC Publishes Guidelines on Filing Standard Contract for Cross-Border Transfer of Personal Information

国家网信办公布《个人信息出境标准合同备案指南》

On May 30, 2023, the Cyberspace Administration of China (CAC) released the first edition of its *Guidelines for Filing the Standard Contract for Outbound Cross-Border Transfer of Personal Information* (Guidelines), just one day before the effective date of the *Measures for the Standard Contract for Outbound Cross-Border Transfer of Personal Information* (Measures). For more details on the Measures, see [GT China Newsletter, Q1 2023](#)). The Guidelines provide more details on filing methods, filing processes, required documents and results for the Standard Contract for Outbound Cross-Border Transfer of Personal Information (Standard Contract).

According to the Guidelines, in the filing process, the personal information (PI) processor should pay special attention to the timeline: (i) within 10 working from when a Standard Contract is approved and in effect, the PI processor must file the Standard Contract with the local provincial cyberspace administration authority; and (ii) the PI processor must file for the Standard Contract within three months after completion of Personal Information Security Impact Assessment (PIA); in other words, the PI processor must enter the Standard Contract within about 10 weeks after completion of PIA. The above timeline applies to outbound cross-border transfer of PI since June 1, 2023. Under the Measures, there is a further grace period of six months, to Dec. 1, 2023, for the PI processor to bring their transfers that occurred before June 1, 2023, into compliance.

According to the Guidelines, if the cyberspace administration authority notifies the PI processor that the filing is unsuccessful, the PI processor should submit additional documents as required within 10 working

days. If the filing is successfully completed, the PI processor will receive a filing number issued by the cyberspace administration authority.

Health & Life Science

National Medical Products Administration Seeks Public Comment on Tightening the Regulation of Marketing Authorization Holders for Entrusted Production of Drugs

国家药监局拟加强委托生产药品上市许可持有人监管

On May 24, 2023, the National Medical Products Administration issued for public comment the *Circular on Tightening the Regulation of Marketing Authorization Holders for Entrusted Production of Drugs (Draft for Comment)* (the “Draft”), aiming to implement market authorization holders’ main responsibilities of ensuring drug quality and safety and strengthening drug production supervision and management. The public comment period closed June 23.

The Draft proposed 17 initiatives to strengthen license management of production entrusted to contract development and manufacturing organizations, strengthening quality management of such production, and strengthening supervision and inspection of market authorization holders. The Draft also introduced the *Guidelines for On-site Inspection of Entrusted Manufacturing of Drugs for Marketing Authorization Holders* to guide the supervision and inspection of market authorization holders.

China Unveils Implementing Rules on the Administration of Human Genetic Resources

科技部公布《人类遗传资源管理条例实施细则》

On June 1, 2023, the Ministry of Science and Technology (MST) issued *Implementation Rules for the Regulations on the Management of Human Genetic Resources* (“Implementing Rules”), effective July 1, 2023, established under the *Biosecurity Law of the People’s Republic of China and the Administrative Regulations of the People’s Republic of China on Human Genetic Resources* (“Measures”). As a practical chapter of the regulatory framework, the Measures provide guidance for compliance with the Measures.

The Implementing Rules mainly address the following issues:

- Further clarify the scope of “Human Genetic Resources Information.”

Under the Measures, human genetic resources (HGR) information refers to the data and other information generated from using HGR materials, for instance, human gene and genome data. The Implementing Rules further clarify that clinical data, imaging data, protein data and metabolic data are excluded from HGR information.

- Authorized regulatory authorities.

The Implementing Rules specify that MST, as the supervisory authority of HGR issues, may entrust relevant agencies to work related to formality examination (i.e., a preliminary review to check whether all the documents are complete, etc.) and technical review of the application materials for administrative licensing regarding HGR, as well as record-filing, prior reporting, supervisory inspection, administrative punishment or other work regarding HGR. For instance, in Shanghai, the Shanghai Human Genetic Resources Administration Service Station was established to conduct part of HGR supervision.

- Emphasize data protection and national security.

The Implementing Rules emphasize data protection and national security and stipulate that when circumstances require HGR data to be disclosed or shared to foreign entities, MST must conduct a security review, e.g., sharing HGR information that is of important genetic family linkages or sharing HGR information in a specific area.

The “foreign party” is prohibited from collecting or preserving China’s HGR and is prohibited from providing China’s HGR to any overseas recipient. Per the Measures, “foreign party” refers to organizations and institutions established or controlled by overseas organizations or individuals. And the Implementing Rules further clarify that “control” means: (i) holding more than 50% of shares, equity, voting rights, or similar rights and interests, either directly or indirectly; (ii) (if (i) is not satisfied) holding voting rights or similar rights and interests, either directly or indirectly, that have a material influence on the institution’s decision-making, management, etc.; or (iii) has material influence on the institution’s decision-making, management via investment, agreement, etc. Institutions registered in Hong Kong or Macao, but controlled by Chinese entities, will not be treated as “foreign parties.”

While there are restrictions, the “foreign party” can conduct international scientific research with Chinese partners. Below are key procedural steps the “foreign party” must take to facilitate the cooperation:

- Submit the ethics review results of their residence country/region;
- Apply for administrative licensing for international cooperation;
- If an international collaborative clinical trial is conducted to obtain marketing approval in China for drugs or medical devices and does not involve the export of HGR, the administrative licensing is not mandatory, but the filing with the MST is necessary;
- Obtain written informed consent from HGR providers;
- Make sure that Chinese partners have substantively participated in the whole research process and have shared rights and interests;
- Jointly submit a research cooperation report to the MST within six months after expiration of the administrative license or filed record;
- Submit a change application to the MST if there’s a change in any material issue, such as number or content of the collection, applicant, etc.

Private Equity Funds

Asset Management Association of China Solicits Comments on Guidelines for the Operation of Private Securities Investment Funds

中基协就《私募证券投资基金运作指引》征求意见

On April 28, 2023, Asset Management Association of China (AMAC) issued draft *Guidelines for the Operation of Private Securities Investment Funds* (Draft Guidelines), proposing regulatory requirements for the fund raising, investment and operation management of private securities investment funds established in mainland China.

Highlights of the Draft Guidelines include:

- Private securities investment funds must have at least RMB 10 million yuan under management to remain in operation. If the net value of fund's assets is under RMB 10 million for 60 business days consecutively, the fund should be liquidated.
- If a private securities investment fund invests primarily in assets, derivatives, or offshore assets with low liquidity, then the risk rating of the investor will not be lower than the risk rating of the fund.
- The manager of the private securities investment fund should conduct due diligence over the source of investor funds. The investors or their designated third parties may not give investment orders or be responsible for investment operation by themselves.
- If private securities fund managers are controlled by the same actual controller with a combined fund management scale of more than two billion yuan at the end of the most recent year, such managers must report monthly information on the fundraising situation, investment operation and investors of the private securities investment funds, as well as the affiliated parties of the private fund managers to AMAC.

** This GT Newsletter is limited to non-U.S. matters and law.*

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