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[National]2021 Key work points about correcting misconducts in pharmaceutical procurement and medical services.

National Health Commission and other authorities jointly released on April 27, 2021 the key work points in 2021 about correcting misconducts in pharmaceutical procurement and medical services.

According to this circular, the authorities will initiate campaigns in 2021 against (a) vaccine-related crimes, (b) illegal actions in the field of nucleic acid testing, (c) red envelop, (d) commercial bribery such as paying/accepting kickback, etc... Amongst, the authorities will implement credit ratings on the involved drugs and medical consumables, and also take restrictive measures against the involved company such as restricting or suspending online listing, purchasing and disclosing dishonest information.

[National]Ministry of Commerce publishes guiding opinions to promote establishment of internal compliance mechanism for export control of dual-use items by exporters.

Following the publication of Export Control Law in October 2020, Ministry of Commerce released on April 28, 2021 the "Guiding Opinions on Establishing the Internal Compliance Mechanism for Export Control by Exporters of Dual-use Items" (the "Guiding Opinions"). According to the Guiding Opinions, the internal compliance mechanism for export control shall have the basic elements such as (a) drafting policy statement, (b) establishing organizational structure, (c) comprehensive risk assessment, (d) establishing examination procedures, (e) developing emergency measures, etc...

The Guiding Opinions include a detailed "Internal Compliance Guide for the Export Control of Dual-use Items" to provide the exporters with specific reference.

[National]NMPA Regulates Quality Management of Clinical Trials of Medical Devices.

The National Medical Products Administration (the "**NMPA**") released on May 10, 2021 the Specifications for Quality Management of Clinical Trials of Medical Devices (Revised Draft for Comment) to solicit public opinions until May 30, 2021.

The document clarifies and strengthens the responsibilities of relevant parties involved in clinical trials of medical devices. It underscores the responsibility of the sponsor, and introduces the concept of risk management, providing that the quality management system of the sponsor should cover the whole process of clinical trials of medical devices. It also enhances the responsibilities of institutions and researchers conducting clinical trials of medical devices, with the duties of the relevant regulators clarified.

The authorities also released six other documents including the Sample Protocol of Clinical Trials of Medical Devices (Draft for Comment) for public comment until May 30, 2021.

[National]China to Strengthen Capabilities in Drug Administration.

The General Office of the State Council released on May 10, 2021 the Implementation Opinions about Enhancing Capabilities in Drug Supervision and Management. The document outlined 18 key tasks, including improving legal framework and optimizing the drug information traceability system.

The document urged building a national platform for drug tracing and improving the application of Internet technologies in drug supervision. A national platform can be established to trace the whole life cycle of medicines, and sole label can be introduced for medical devices. The document proposed applying big data to supervision of drugs, medical equipment and cosmetics, and using the industrial internet in overseeing vaccines, blood products and special drugs. The document also emphasized efforts to improve the review and testing system for drugs, medical equipment and cosmetics.

[National]MCT Plans to Allow Foreign Investors to Establish Entertainment Venues in China.

The Ministry of Culture and Tourism (the "**MCT**") recently released the Circular about Adjusting Approval Matters for Entertainment Venues and Internet Service Locations (Exposure Draft) (the "**Circular**"), to gather public opinions until May 14, 2021.

According to the Circular, foreign investors are allowed to set up entertainment venues in China, without restrictions on the proportion of investment. Foreign investors can file applications with provincial department of culture and tourism to set up entertainment venues, and they shall meet the same conditions and follow the same approval procedures as domestic applicants. Investors from Hong Kong, Macau and Taiwan will be treated the same as foreign investors.

[National]The Administrative Measures for Credit Repair (for Trial Implementation) (Draft released on May 12, 2021 for public comments).

It worth noting that these Measures define the conditions for terminating publicity, shielding or deleting the information of administrative punishment. However, the criminal punishment information of a legal person and non-legal person organization shall be kept and publicized permanently on the website of credit platform, and the publicity shall not be terminated, blocked or deleted.

[National]Personal Information Protection Law (Second draft for review, released on April 29, 2021).

The second draft has made important adjustments in the burden of proof. The first draft stipulates that if personal information processing activities infringe upon the rights and interests of personal information, and the personal information processor can prove that he is not at fault, he may be relieved or exempted from liability. The second draft amended this as: if the personal information rights and interests are infringed due to personal information processing activities, and the personal information processor can not prove that he is not at fault, he should bear the tort liability such as damages.

[National]Data Security Law (Second draft for review, released on April 29, 2021).

The second draft defines the responsibility and basis for defining important data, and requires all regions and departments to determine the specific catalogue of important data in their own regions, departments and related industries and fields. In addition, the second draft improved and refined the provisions on data cross-border flow security management. Although the Cybersecurity Law requires data cross-border flow security management, it is limited to data about "critical information infrastructure". The second draft makes more comprehensive and detailed provisions on this, fills in the absence and loopholes of non-critical infrastructure data.