國楓律師事務所
GRANDWAY LAW OFFICES

Newsletter

Update October 14, 2019

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Update

Further Opening of China's Financial Service Industry

China has accelerated its pace to open up its financial service industry to foreign investment.

On October 14, China's Securities Regulatory Commission ("CSRC") announced that it will lift restrictions on foreign investor's equity interest in Chinese securities firms, fund management firms, and futures brokerage firms one year earlier than previously announced. From January 1, 2020, all restrictions on foreign shareholding interest in Chinese futures brokerage firms will be removed. From April 1, 2020, all restriction on foreign shareholding ratio in Chinese fund management firms will be removed. From December 1, 2020, all restrictions on foreign shareholding interest in securities firms will be removed.

On September 10, 2019, the State Administration of Foreign Exchange ("SAFE") cancelled the investment quota limitations of qualified foreign institutional investors (QFII) and RMB qualified foreign institutional investors (RQFII). The qualified foreign investor scheme has important significance for the opening-up and healthy development of Chinese financial markets. This is another major reform measure after abolishing relevant exchange restrictions in 2018.In the future, foreign institutional investors with corresponding qualifications will only need to go through registration procedure, so as to remit funds independently to make securities investment in accordance with the regulations. It will be more convenient for foreign investors to participate in the domestic stock and bond market.

Enforcement against Online Marketing Stepped Up

On June 18, 2019, eight ministry level departments including the State Administration for Market Regulation, the National Development and Reform Commission, the Ministry of Industry and Information Technology, the Ministry of Public Security, the Ministry of Commerce, the General Administration of Customs, the Cyberspace Office and the State Post Bureau have jointly issued the 2019 Plan of Special Action for Online Market Regulation (the "Plan"), which is also kwon as the "Network Sword Action". This special action was jointly launched by all aforesaid departments and would last five months from June to November.

The Plan states that the Network word Action will focus on inspecting and regulating the behaviors of e-commerce business operators including their qualifications. Efforts will be made to severely crack down upon online sales of counterfeit and shoddy products, unsafe food, quack medicine and inferior-quality drugs, and upon online false advertising, conclusion of false transactions to drive up the credit standing, illegal tied sales, and other unlawful acts. Furthermore, the Plan calls for stronger efforts to identify, regulate, clamp down, investigate and punish unlawful activities via mobile Apps, including online trading platforms, online food ordering and delivery platforms, online tourism platforms, SNS-based e-commerce platforms, cross-border e-commerce platforms and other new forms of online marketing adding that regulation of entrusted purchases from overseas will be tightened and the import/export process will be rectified and strictly scrutinized for cross-border e-commerce business.

Data Protection of Children's Internet Personal Information

The Cyberspace Administration of China ("CAC") has recently issued the Regulations on the Protection of Children's Internet Personal Information (the "Provisions"), with effect from October 1, 2019. It is the first cyber protection law in China specifically aiming to protect children.

The Regulations stipulate that network operators shall establish specific rules for protection of children's personal information and user agreement, and designate personnel to specially take charge of protecting children's personal information. According to the Regulations, network operators that collect, use, transfer or disclose personal information of children shall, in a notable and clear way, notify children's guardians of their practices, and obtain the consent from children's guardians. Also, network operators are required to provide the guardians with an option for refusal and notify the guardians of why, how and to what extent they will collect, store, use, transfer, or disclose children's personal information while seeking the consent from the guardians.

Any failure of adequately performing duties as stipulated under the Regulations, the network operators will be required to make correction or imposed a fine by relevant authorities as the case may be.

Shanghai Free Trade Zone Expanded with New Incentives and Policies

On August 6, 2019, China's State Council issued an overall plan for the establishment of new Lingang area of the China (Shanghai) Pilot Free Trade Zone (the "Plan"), which will be located in the southeast tip of Shanghai with a start-up area of 119.5 square kilometers ("Lingang New Area").

Lingang New Area aims to facilitate investment and operations base on fair competition norms. Thus, Lingang New Area will remove unnecessary trade regulation, licensing, and procedural requirements to facilitate foreign investment and capital flows and realize the free flow of goods/services. According to the Plan, Lingang New Area will increase openness in key sectors such as informational technology, smart equipment, bio-medical, new energy and smart vehicle, education and will encourage innovative cross-border e-commerce services. In addition, the government will further offer tax cuts, duty exemption and access to other beneficial policies to attract investment.

The Plan is still general in nature. More detailed implementation rules from local government authorities are to be made in

the coming months. On September 18, Shanghai issued “Certain Opinions on Further Promoting Foreign Investment” which identified sectors to be promoted and measures to further protect interests of foreign investors, and also offered targeted incentives.

On September 20, Shanghai issued measures to promote innovations in financial industry in Lingang New Area with a focus on cross-border capital movement and cash management and trial of free flow of capital and free conversion of foreign exchange.

Article(s)

Implications of China’s New Drug Law

by David Zou; Kerry Zhang

The Chinese legislature passed major amendments to the Drug Administration Law (“DAL”) on August 26, 2019 which will take effect on December 1, 2019. The new DAL entails many changes which will make China’s drug administration smarter, more reasonable, and pro-innovation. Below is an analysis of the major changes and their implications.

1. Online sales of prescription drugs.

The new DAL takes a more lenient and open but cautious approach to online sale of prescription drugs. Except for certain high-risk pharmaceutical products such as vaccines, blood products, anesthetics, psychotics, medical toxins, radioactive drugs, and precursor chemicals, online sale of prescription drugs is not entirely prohibited, but it must satisfy the drug sales provisions of the DAL as well as separate regulations to be issued by the National Medical Products Administration (“NMPA”). It is reported that measures under consideration include: (1) drug distributors eligible for online sales must be an entity with drug distribution license; (2) drug online sales network must be interconnected with the medical institutions' systems to achieve information sharing and to ensure genuine prescription and drug safety of the patients; (3) drug dispensing and delivery shall meet the GSP requirements. As can be expected, e-pharmacy is approaching in China.

2. Revised definition of counterfeit and inferior drugs

The current DAL treats unapproved drugs as counterfeit drugs and the importing and selling of such unapproved drugs as criminal offenses. The new DAL’s definition focuses on active ingredients and claims, rather than regulatory approvals. In particular, counterfeit drugs refers to: drugs with ingredients inconsistent with national drug standards; non-medical ingredients passing off as drugs or one drug passing off as another drug; deteriorated drugs; drugs with indication beyond actual scope of indication or function. However, importing and selling unapproved drugs in large quantities is still illegal which may implicate regulatory punishment such as fines, confiscation of illegal gains or even administration detention, but not criminal liability. Yet, if only a "small amount" of foreign marketed drugs are imported into China without authorization, there could be an exemption from punishment or lesser punishment.

3. Local agent requirement

The new DAL requires foreign pharmaceutical companies to appoint a legal agent in China. The legal agent will need to assume the same regulatory obligations and liability as the foreign marketing authorization holder. If a MAH is a foreign company, its designated business entity in China shall perform its MAH obligations and bear joint and several liabilities with the foreign MAH.

4. Enhanced drug market authorization holder system

Following a 3-year pilot project in 10 provinces/municipalities to implement an enhanced Drug Market Authorization Holder ("MAH") system, the new DAL will implement this enhanced MAH system nationwide. The enhanced MAH system separates marketing authorization from manufacturing authorization. A MAH can either directly manufacture and sell or contract out to third party to manufacture and sell. A MAH can also transfer its market authorization to qualified third parties upon approval. Under the new DAL, the responsibilities to ensure drug safety, efficacy and quality are imposed on a MAH for the entire life-cycle of a drug such as non-clinical research, clinical trial, production and sales, post-market research, adverse reaction monitoring, reporting and handling of drugs.

5. Encouraging drug innovation

The new DAL puts particular emphasis on the development of new drugs for the treatment of serious life-threatening diseases, rare diseases and paediatric drugs and the development of traditional Chinese medicine. With respect to clinical trial approval, bioequivalence studies require filing (not approval) with NMPA. For clinical trials that require approvals, if NMPA fails to decide within 60 working days upon receiving a clinical trial application, an authorization shall be deemed to be granted. Moreover, priority review and approval pathways are provided for paediatric drugs, drugs with urgent clinical needs, new drugs for prevention and treatment of severe infectious diseases and rare diseases. NMPA is also required to conduct the review and approval for a drug application at the same time as the review of the drug's API, drug excipients, packaging materials and containers, the compliance of drug quality standards, production processes, labels, and drug inserts. The new DAL allows conditional market authorization approval for drugs to treat serious life-threatening diseases with no comparable treatment options and drugs for an urgent public health need if mid-stage clinical data can predict clinical benefits. The new DAL allows compassionate drug use if a clinical institution is conducting clinical trial of a drug to treat life-threatening disease with no comparable treatment options, the drug being tested can be available to other patients with the same conditions in the same clinical trial institution, provided that the drug being tested is likely to have benefits and has passed the ethical review and informed consent has been obtained from the patients.

6. Shift in supervision focus

The new DAL replaces the current static pre-approval supervision and certification system with a dynamic post-approval inspection and enforcement system. Pharmaceutical manufacturers and distributors need to be prepared for fly-in inspections at an increased frequency. The NMPA will expand its inspection force to more effectively supervise the operations of pharmaceutical companies, both at home and abroad, as well as their vendors and suppliers. During drug post-marketing management stage, a MAH shall form a risk management plan and conduct post-marketing research and assess regularly on the safety, efficacy and quality of listed drugs. The new DAL also requires a MAH to monitor and report adverse drug reactions, recall drugs with quality defect or other safety risks, and report annually to the provincial NMPA regarding their drug production and sale, post-marketing research and risk management measures. The legal representative and principal persons of a MAH are also required to take full responsibility for the drug quality.

7. First accountability system

The new DAL provides a first accountability system which enables victims of poor drug quality to claim compensation either from the MAH, the drug manufacturer, the drug distributor or the medical institution. The party being asked to bear the compensation in advance can seek to recover the compensation from the party who is actually responsible for the drug quality problem.

8. Enhanced penalties

Failure to comply with the statutory obligations will result in more severe penalties, both in the scale of fines and in the forms of sanctions. For example, falsification of regulatory approvals and regulatory dossiers will result in increased fines (from up to three to 15 times the illegal proceeds). The fine for unlicensed production and sale of drugs has been raised from 2-5 times to 15-30 times of the drug product value. Moreover, the legal representative and main responsible persons of the company will face new sanctions, including 10 years of debarment and detention by the police. The new DAL also imposes legal liabilities on local drug administration authorities. For example, if the local government fails to report or delays in reporting significant drug safety incidences, the responsible officers in the drug administration or supervision authorities could be demoted or even dismissed.

9. Implications for foreign drug companies

The new DAL shows China's determination to implement the most stringent drug regulation in terms of drug supervision, punishment and accountability system. It opened door for more foreign drug companies to enter China in CMO, generic medicine manufacturing, foreign drug distribution, online sales. The MAH system will provide more flexibility in structuring cross-border transactions. Subject to the NMPA’s approval, market authorizations can be transferred from one company to another without changing contract manufacturers. These changes may enable Chinese MAHs to work with overseas CMOs and foreign MAHs to work with Chinese CMOs and to restructure their supply chains. Foreign companies will be more willing to transact with Chinese companies to divest their product portfolios or localize the production of their assets in China. However, there are certain deficient areas that need to be addressed. The new DAL is silent on regulatory data protection in medical industry which will require other laws and regulations as well as judicial practices to complement.

Contact Us

Grandway Law Offices (Shanghai)

www.grandwaylaw.com

23F, S2 Building, Bund Financial Center, 600 Zhongshan No. 2 Road (E), Shanghai, 200010, China