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Legal Updates

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1. CSRC to Exempt Foreign Investors from Short Swing Profit Rule

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According to news reports issued on October 16, 2022, to further facilitate foreign capital investment in China A shares, the China Securities Regulatory Commission ("**CSRC**") is considering formulating a special exemption rule for the short swing profit rule ("**SSPR**")[1] for foreign investors (e.g. qualified foreign investors/QFIs and foreign investors under the Stock Connect scheme).

Exemption for foreign mutual funds

Under current PRC rules, an investor must generally aggregate its positions with all its concerted parties for purposes of disclosure of interest ("**DOI**") rules[2] and SSPR; thus, in principle, an asset manager must aggregate all the positions held by different products under its management. However, CSRC has granted an exemption from this requirement to domestic mutual funds managed by CSRC-licensed fund management companies ("**FMCs**") with respect to their managed mutual funds (but not private funds or managed accounts); these FMCs may instead opt to comply with DOI rule and SSPR based on the positions held by each single mutual fund ("**CSRC Exemption**").

The CSRC Exemption is currently not available for foreign mutual funds managed by foreign asset managers that invest in A shares either via QFI or the Stock Connect scheme. The foreign asset management community has long been seeking a similar exemption by reference to the CSRC Exemption available to domestic asset managers. In particular, without the CSRC Exemption, managers who manage index-tracking and passive-investment products may easily trigger the reporting and trading limitation thresholds under the DOI rules and SSPR. Such a potential risk has become more realistic after the MSCI inclusion of A shares.

Now, reportedly CSRC is considering granting a special exemption to foreign mutual/public funds managed by foreign managers for SSPR purposes, by reference to the CSRC Exemption. Furthermore, it is anticipated that the same aggregation exemption will also apply for DOI rule purposes from a regulatory consistency perspective.

Exemption for HKSCC

Under Stock Connect rules, Hong Kong Securities Clearing Company Limited ("**HKSCC**") acts as the nominee holder for all foreign investors under the Stock Connect scheme and has been granted an exemption from complying with DOI rules for its nominee holdings. CSRC is also considering clarifying that HKSCC is exempted from complying with SSPR for its nominee holdings as well.

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[1] SSPR refers to that a shareholder holding 5% or more shares or securities with equity nature in a listed company may not sell or purchase such securities in no more than 6 months after purchase or sale (as applicable) of the same; otherwise, the short swing profit shall be vested in the listed company.

[2] DOI refers to the disclosure and trading suspension obligations imposed on a shareholder that holds more than 5% shares or securities with equity nature in a listed company.

Reportedly, CSRC is in the process of formulating the special exemption rule and will officially issue the rule after its internal procedures are completed. This move by CSRC reveals a positive signal to the market particularly the international investors community, which will almost certainly stimulate foreign capital investment in A shares. We will continue to monitor the developments and provide further insight on a timely basis.

2. Measures for Supervision and Administration of Online Sales of Drugs: Analysis of Key Aspects and Impacts

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Background

Fast-growing e-commerce has changed lifestyles and invented new ways of consumption, amid which demand has rapidly increased for Internet-based medical services such as online drug sales and online medical diagnosis. Since the regulation and promotion of "Internet-based healthcare services" was included as part of the Outline of the "Healthy China 2030" Plan, China's Internet healthcare industry has been flourishing, channeled by a series of favorable policy decisions. In the meantime, buoyed by a boom in Internet hospitals and online diagnosis and treatment services, as well as a boost in prescription outflows and volume-based procurement of drugs, the online drug sales market is expected to expand unabated.

The evolution of regulatory policies in China related to online drug sales has been long and convoluted. On the whole, the Chinese government has been open to the online sale of drugs, signaled by the release of the *Interim Provisions on the Examination and Approval of Online Drug Transaction Services*, an upfront regulatory move toward online drug transaction activities as early as 2005. However, as opposed to an open attitude, regulators tended to be conservative in their actual supervision of online drug sales activities. For example, with respect to online sales of prescription drugs, the industry's most controversial issue, the *Provisions for Supervision of Drug Distribution* (effective as of 2007) are in place to prohibit drug manufacturers and distributors from selling prescription drugs directly to the public over the Internet. In addition, there used to be a prolonged silence at the law-level legislation on the direct regulation of online drug sales activities, as it was not addressed in the *Drug Administration Law of the People's Republic of China* ("***Drug Administration Law***") before its amendment in 2019.

The silence was broken in recent years with legislative progress in online drug sales regulation. On December 1, 2019, the current *Drug Administration Law* formally entered into force, delineating for the first time a clear, holistic regulatory framework on online drug sales at the law-level legislation. With respect to the scope of drugs permitted for online distribution, Article 61 of the amended *Drug Administration Law* clarifies that drug marketing authorization holders ("**MAHs**") and distributors are permitted to engage in online drug sales except for those drugs subject to special administration by the State, provided that they comply with relevant provisions of the *Drug Administration Law* and administrative measures formulated by competent regulatory authorities. Also, online drug trading platform providers ("**third-party platforms**"), as key participants in online drug sales, are subject to several obligations under Article 62, such as filing, examination, supervision, and management of online drug sales on their platforms; Article 131 further sets out legal liabilities imposable on third party platforms which fail to perform these obligations. Thus, the fundamental principles of online drug sales regulation have been established after the current *Drug Administration Law* entered into force, although industry players have expected and long awaited detailed administrative measures.

[3] Han Kun interns Leyi WANG and Shuwen SUN also contributed to this legal commentary.

On April 15, 2021, the General Office of the State Council issued the *Opinions on Helping Ensure Stability on the Six Fronts and Security in the Six Areas and Further Improving the Work Related to the Reforms to "Streamline Administration, Delegate Powers, Improve Regulation and Strengthen Services"* ("***Work Opinions***"), further clarifying the keynote for the regulation of online sales of prescription drugs: On the condition that the authenticity and reliability of electronic prescription sources are guaranteed, prescription drugs are permitted to be sold online, except for those subject to special administration by the State.

On September 1, 2022, the State Administration for Market Regulation ("**SAMR**") formally issued the *Administrative Measures for the Supervision of Online Drug Sales Drug* ("***Administrative Measures***"), following several drafts for public comment. The *Administrative Measures* will come into force on December 1, 2022, and provide detailed rules for implementing the principles of online drug sales regulation established in the current *Drug Administration Law*.

In this commentary, we summarize and comment on key aspects covered by the *Administrative Measures*.

Key subjects of online drug sales

The key subjects engaging in online drug sales include online drug distributors and third-party platforms. Online drug distributors comprise MAHs (manufacturers of traditional Chinese medicine (TCM) decoction pieces are included as an equivalent), drug wholesalers, and drug retailers. The following table provides detailed information of the three types of online drug distributors in terms of their qualifications, distribution requirements, and regulatory departments:

Distributor type	Qualification	Scope of drugs allowed for distribution	Distribution method	Regulatory department
MAH	Obtaining a drug registration certificate (without acquiring a drug distribution license)	Drugs for which the MAH has obtained respective drug registration certificates	Wholesale	Provincial drugs administrations ("**drug administrations**")
Drug wholesaler	Obtaining a drug distribution license (distribution method: wholesale)	Drugs within the approved scope of distribution	Wholesale	Provincial drug administrations
Drug retailer	Obtaining a drug distribution license (distribution method: retail)	Drugs within the approved scope of distribution	Retail	Drug administrations at the level of cities divided into districts or at the county level

With respect to third-party platforms, an earlier draft revision to the *Regulations for the Implementation of*

the Drug Administration Law of the People's Republic of China added a provision as Article 83, stipulating that "third-party platform providers shall not directly engage in online drug sale activities", which aroused heated discussion in the industry. The *Administrative Measures* are silent on this issue, while the National Medical Products Administration ("**NMPA**") only mentions in its official policy interpretation that enterprises engaging in online drug sales must have a brick-and-mortar presence. As we understand, under the *Administrative Measures*, third-party platforms without a drug distribution license can only provide sites for online drug distribution or provide services such as facilitating transactions as a go-between, but cannot enter into online transactions directly as the buyer or seller of drugs. Nonetheless, the *Administrative Measures* do not confront the question of whether third-party platform providers are allowed to acquire a drug distribution license and directly engage in online drug sales. Given that third-party platforms are held responsible for examining, supervising, and administering online drug distributors under the *Drug Administration Law* and the *Administrative Measures*, and thus are vested with a regulatory role that requires impartiality, a third-party platform may face conflict of interest issues and even compliance hurdles if it were to directly sell drugs on its self-owned platform. It is safer for a third-party platform desiring to directly sell drugs online to have a standalone drug distributor affiliate company, which acts to distribute drugs on a platform provided by its affiliate company, in strict compliance with the obligations of online drug distributors and third-party platforms under the *Administrative Measures*. Nevertheless, further exploration is needed to determine whether such standalone drug distribution companies and the other third-party platform providers within the same company group can satisfy relevant compliance requirements, by taking approaches such as installing internal firewalls.

Scope of drugs permitted for online distribution

At the emerging stage of "Internet + drug circulation", online drug sales were tightly regulated, where the sales of prescription drugs on the Internet was entirely prohibited. Regulations such as the current *Drug Administration Law* and the *Work Opinions* gradually expanded the scope of drugs permitted to be sold online. The *Administrative Measures*, consistent with the current *Drug Administration Law*, only impose an explicit ban on online sales of medicines subject to special administration by the State, such as vaccines, blood products, narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive drugs, and pharmaceutical precursor chemicals, and those prohibited for online sales as provided for in a detailed catalogue to be developed by the NMPA.

However, the opening up of drug categories permitted for online sales is only the beginning. In regard to the online sales of prescription drugs and other drugs with higher risks in clinical use, online drug distributors, third-party platforms, Internet hospitals, and other participants in the Internet healthcare industry will share challenges arising from drug storage, transportation, clinical use, adverse drug reaction monitoring, and other aspects of online drug sales, which also open doors for in-depth advancement of the Internet healthcare industry.

Primary responsibilities of online drug distributors

Chapter II of the *Administrative Measures* specifies the primary responsibilities of MAHs, drug wholesalers, and drug retailers engaging in online drug sales to regulate their relevant practices. In addition to the

general responsibilities of all online drug distributors, the *Administrative Measures* further set out special obligations to be fulfilled by online drug retailers. The following table provides a breakdown of these responsibilities and obligations.

Subject	Administrative aspects	Specific requirement
Online drug distributors	Internal management system	Online drug distributors shall establish and implement systems in respect of drug quality and safety control, risk control, drug traceability, storage and delivery management, adverse reactions reporting, and complaint response, among others.
	Information reporting	Online drug distributors shall report information such as their corporate name, website name, application program name, IP address, domain name, drug manufacturing license, or drug distribution license to the relevant drug administration. Any change to the above information shall be reported within 10 working days.
	Publication of license information	Online drug distributors shall continuously publicize information on their drug manufacturing license or drug distribution license at a prominent location on the homepage of their website or the main webpage of their business activities. Any change to the above information shall be updated within 10 working days.
	Display of drug information	The relevant drug information displayed by an online drug distributor shall be true, accurate, and legitimate.
	Recordkeeping	Online drug distributors shall keep the qualification documents of suppliers, electronic transaction records, and other records in a complete manner. The relevant records shall be kept for at least five years, which shall not end within one year after the expiry date of the relevant drugs.
	Quality and safety control	Online drug distributors shall take appropriate risk control measures in accordance with law for drugs with quality problems or potential safety hazards, and shall promptly disclose corresponding information on the homepage of their website or the main webpage of their business activities.
	Emergency response	In the event of public health emergency or other emergency that poses a serious threat to public health, an online drug distributor must comply with the relevant emergency response provisions of the State and adopt the corresponding control and response measures pursuant to law.
	Drug recall	Where an MAH recalls drugs pursuant to law, the relevant online drug distributor must actively cooperate in the recall of drugs.
Online drug retailers	Drug promotion	Online drug retailers shall not, in violation of relevant provisions, give away prescription drugs or Class A OTC (over-the-counter) drugs to individuals as free gifts bundled with purchased drugs or commodities, or in any other way.

Subject	Administrative aspects	Specific requirement
	Prescription management	Online drug retailers shall ensure the authenticity and reliability of prescription sources and adopt a real-name authentication system.
		Online drug retailers shall enter into agreements with providers of electronic prescriptions, examine and dispense prescriptions in strict accordance with relevant provisions, and mark used electronic prescriptions to avoid repeated use of prescriptions.
		Where prescriptions received by an online drug retailer are photocopies of paper prescriptions, the online drug retailer must take effective measures to avoid repeated use of such prescriptions.
	Online pharmaceutical service system	Online drug retailers shall establish an online pharmaceutical service system, where legally qualified pharmacists or other pharmaceutical professionals shall carry out tasks such as examining and dispensing prescriptions and giving guidance for rational use of drugs.
	Publication of operator information	Online drug retailers shall continuously publicize qualification certification information, etc. of their legally hired pharmacists or other pharmaceutical professionals at a prominent location on the homepage of their website or the main webpage of their business activities. Any change to the above information shall be updated within 10 working days.
	Information display for prescription drugs	Online drug retailers selling prescription drugs shall, on each drug display webpage, highlight such risk warning messages as "prescription drugs must be purchased and used on the strength of prescriptions under pharmacists' instruction". Prior to the sale of prescription drugs, the online drug retailer shall fully inform consumers of relevant risk warnings, which consumers should confirm as a sign of their acknowledgement.
		Online drug retailers shall separately display prescription drugs and OTC drugs, and prominently label prescription drugs and OTC drugs on their respective webpages.
		Online drug retailers shall not directly display the package, label, or other information of prescription drugs on the homepage or start page for prescription drug sales. Without the review and approval of relevant prescriptions, an online drug retailer shall not display information such as the instructions for users (**IFU**s) of prescription drugs, nor shall it provide any service related to purchase of the prescription drugs.
	Drug delivery	Online drug retailers shall be responsible for the quality and safety of drug delivery. Appropriate transport methods and facilities shall be selected according to the quantity of drugs, the distance and duration of transportation, temperature and humidity requirements, etc. Drugs being delivered shall be placed in separate spaces and

Subject	Administrative aspects	Specific requirement
		be clearly marked, relevant requirements shall be met, and the entire delivery process shall be traceable.
		Where an online drug retailer entrusts drug delivery to a third-party service vendor, it shall examine the quality control system of the entrusted vendor, enter into a quality agreement with the entrusted vendor specifying drug quality accountability, operation procedures and other contents, and shall supervise the entrusted vendor.
	Sales voucher	Where drugs are sold to individuals, sales vouchers shall be issued in accordance with relevant provisions. Sales vouchers may be issued in electronic form, and sales records of the smallest drug sales unit shall be clearly retained to ensure traceability.
	Record keeping	An online drug retailer selling prescription drugs shall keep records of prescriptions, online pharmaceutical services, etc. The relevant records shall be kept for at least five years, which shall not end within one year after the expiry date of relevant drugs.

Notably, under the *Administrative Measures*, online drug retailers are required to establish an online pharmaceutical service system. In this regard, Article 52 and Article 58 of the current *Drug Administration Law* provide that enterprises engaging in drug distribution should be staffed with legally qualified pharmacists or other pharmaceutical professionals who will be responsible for drug management, prescription review and dispensing, providing guidance for rational use of drugs, etc. In addition, as provided in the NMPA's *Circular on Regulating Licensed Pharmacist Staffing in Drug Retailers* issued in 2020, "In principle, drug retailers dealing in prescription drugs and Class A OTC drugs shall be staffed with licensed pharmacists; drug retailers only dealing in Class B OTC drugs shall be staffed with business personnel who have passed examinations organized by relevant drug administrations." Following the above, Article 10 of the *Administrative Measures* require online drug retailers to "establish an online pharmaceutical service system where legally qualified pharmacists or other pharmaceutical professionals shall be responsible for examining and dispensing prescriptions, giving guidance for rational use of drugs, etc.", showing consistency in China's regulatory requirements for online and offline drug sales.

The *Administrative Measures* also set forth requirements to regulate drug delivery in online drug retailing. Prior to the *Administrative Measures*, there was no clarification under the *Good Supply Practice for Pharmaceutical Products* ("**GSP**") or other regulations in China to regulate end user delivery in drug retailing. The current GSP only requires enterprises in general to take effective quality control measures during drug transportation to ensure the quality of drugs, and to develop a drug tracking system to realize the traceability of drugs. It also sets out detailed quality control requirements for drug transportation and delivery in drug wholesale activities. In addition, the current *Drug Administration Law* stipulates that, where MAHs, drug manufacturers, or drug distributors entrust a third party to store or transport drugs, they are required to assess the entrusted party's quality assurance and risk management capacity, sign an entrustment agreement with the entrusted party to specify matters such as drug quality accountability and operation procedures, and supervise the entrusted party. In our opinion, drug retailers, as the party carrying out drug distribution and holding a drug distribution license, should be responsible for ensuring

that their drug transportation and delivery meets GSP standards and other relevant requirements. However, the absence of more specific rules gave rise to controversy over the legality of a widely adopted business model in practice where online drugstores would use courier services to deliver drugs to consumers. For now, the *Administrative Measures* provide a response to this gap. Article 14 of the *Administrative Measures* clearly requires that online drug retailers be responsible for the quality and safety of drug delivery, that appropriate transport methods and facilities be selected according to the quantity of drugs, the distance and duration of transportation, temperature and humidity requirements, etc., and that drugs being delivered be placed in separate spaces and clearly marked, so as to ensure that relevant requirements are met and the entire delivery process is traceable. Article 14 also expressly allows online drug retailers to entrust drug delivery to a third-party service vendor, where they shall examine the quality control system of the entrusted vendor, enter into a quality agreement with the entrusted vendor to specify such matters as drug quality accountability and operation procedures, and supervise the entrusted vendor. In addition, Article 17 of the *Administrative Measures* requires third-party platforms to establish a system to manage delivery of drugs sold on their platforms. Thus viewed, the *Administrative Measures* in fact recognize the widely available business model adopted by online drug retailers in practice, and meanwhile specify the obligations and responsibilities of online drug retailers and third-party platforms in their business activities under this model. We will also keep a close eye on more specific delivery requirements regarding online drug retailing, which will be issued by the NMPA in the future.

Regulation on online sales of prescription drugs

As mentioned above, the online sale of prescription drugs remains a controversial issue in China, as it was explicitly prohibited by the *Provisions for Supervision of Drug Distribution*, a department-level regulation. The prolonged ban has only been relaxed gradually in recent years. As amended in 2019, the *Drug Administration Law* does not contain a provision proposed in an earlier draft that would have prohibited drug distributors from "directly selling prescription drugs through third-party platforms for online drug sales". The 2021 *Work Opinions* give a conditional nod to online sales of prescription drugs with certain exceptions, while the *Administrative Measures* further affirm the legality of selling prescription drugs over the Internet. Although the *Provisions for Supervision of Drug Distribution* are still in force, the *Administrative Measures*, of equal effect as another department-level regulation, should prevail based on the conflict of laws principle that "the later prevails over the earlier in conflict of laws of the same level". While recognizing the legality of online sales of prescription drugs, the *Administrative Measures* further set out relatively rigorous requirements for the management of online sales of prescription drugs to ensure safe use of drugs by patients.

I. Prescription management

With respect to prescription management, Article 9 of the *Administrative Measures* stresses that, where prescription drugs are sold to individuals over the Internet, the authenticity and reliability of prescription sources must be ensured, and a real-name authentication system must be adopted. Online drug retailers accepting electronic prescriptions are required to enter into agreements with the electronic prescription providers, examine and dispense prescriptions in strict accordance with relevant provisions, and mark used electronic prescriptions to avoid repeated use of such prescriptions. Third-

party platforms that accept electronic prescriptions are required to verify information of the electronic prescription providers and enter into agreements with them. The *Administrative Measures* also allow online drug retailers to accept photocopies of paper prescriptions, provided that they must take effective measures to avoid repeated use of such prescriptions.

"Repeated use of prescriptions" and the way to avoid it remains a widely discussed issue in the industry. Article 9 of the forthcoming *Administrative Measures*, compared with its public comment draft in 2020, provides more specific and rigorous rules, which give clearer instructions for online drug retailers and third-party platforms to perform their obligations related to prescription management. It also emphasizes use of the real-name authentication system when managing prescriptions and requires effective measures to be in place to avoid the repeated use of prescriptions. These rules show a prudent attitude held by the Chinese government toward online sales of prescription drugs.

II. Information display and sale process

In respect of information display for prescription drugs, online drug retailers will be subject to strict requirements under Article 13 of the *Administrative Measures*, which include:

- On each drug display webpage, highlighting risk warning messages such as "prescription drugs must be purchased and used on the strength of prescriptions under pharmacists' instruction";
- Separately displaying prescription drugs and OTC drugs, and prominently labelling prescription drugs and OTC drugs on their respective webpages;
- No publication of the package, label, or other information of prescription drugs on the homepage or start page for prescription drug sales;
- No display of information such as the IFUs of prescription drugs and no provision of any service related to the purchase of prescription drugs without the review and approval of relevant prescriptions.

Article 13 of the *Administrative Measures* effectively echoes relevant provisions in the current *Advertising Law* and other rules and regulations concerning prescription drug advertising. Both the *Advertising Law* and the *Interim Measures for Examination and Administration of Advertisements of Drugs, Medical Devices, Health Food and Formula Foods for Special Medical Purposes* stipulate that prescription drug advertisements can only be published in professional medical or pharmaceutical journals jointly designated by the National Health Commission of the PRC and the NMPA. In practice, however, some online drug sellers display the package and IFUs of prescription drugs on their webpages purporting to "protect consumers' right to be informed", which is a common but controversial practice given that it may violate the above regulatory rules on prescription drug advertising. The forthcoming *Administrative Measures* provide a clear direction for parties concerned to legally display prescription drug information, and confirm that drug distributors who engage in such direct display practices will face compliance risks.

As we understand, pursuant to Article 13 of the *Administrative Measures*, only the generic name, brand name or similar information of a prescription drug can be directly displayed to the public on the

homepage and start page for its sales; other information such as the IFUs can only be provided to consumers who have had their relevant prescriptions reviewed and approved. In our opinion, however, Article 13 also invites questions that remain to be further clarified by regulatory authorities in the future – questions such as: Which specific information can be publicized on the homepage and start page for selling a prescription drug? Can information such as drug specifications and indications be publicized? How to define the scope of "the homepage and start page for selling a prescription drug"? Does it mean that online drug sellers can attach a link on the drug selling interface which directs to a webpage, where the package, label, and other information of a prescription drug can be displayed?

As for the sale process of prescription drugs, before the *Administrative Measures*, online sales of prescription drugs in China mostly followed a "drug first, prescription second" pattern, where consumers search, find, and order prescription drugs on the platform before relevant prescriptions are issued through doctors' inquiry and affirmation at the payment step. This pattern will be replaced by a "prescription first, drug second" model stressed by the *Administrative Measures*, where prescription approval will come before the order and purchase step and serve as a prerequisite to entering that step. This change is consistent with existing rules such as the one stipulated in the *Rules for Supervision and Administration of Online Medical Diagnosis (for Trial Implementation)* issued for immediate implementation in February 2022, where "provision of prescription drugs to patients before the issuance of the corresponding prescriptions is strictly prohibited". Thus, as we understand, after the *Administrative Measures* enter into force, consumers who wish to purchase prescription drugs online will need to follow the process below:

- Search for the drug name to find the prescription drug they need, and click the relevant link to open the relevant webpage;
- File for prescription review and obtain a pharmacist's approval of the prescription;
- Obtain access to the IFUs and other information of the prescription drug, and make an order for purchase.

In addition, prior to the sale of prescription drugs, online drug retailers should fully inform consumers of relevant risk warnings, which consumers should confirm as a sign of their acknowledgement.

Obligations of third-party platforms

Third-party platforms, as key responsible entities engaging in online drug sales, are subject to certain obligations under the current *Drug Administration Law* to supervise and administrate online drug selling activities. The forthcoming *Administrative Measures* implement the platform obligation requirements set forth in the *Drug Administration Law* and make further refinements, particularly emphasizing platforms' internal management obligations to consolidate their role as responsible subjects in online drug sales, which will serve to enhance the orderly development of online drug sales.

Under the *Administrative Measures*, third-party platforms are required to perform the following administrative obligations:

Administrative aspects	Specific matter(s) involved	Specific requirement
Record filing obligations	Record filing	Third-party platforms shall file for record their corporate name, legal representative, unified social credit identifier, website name, domain name, and other information with the provincial drug administration at their locality.
Internal management	Organization	Third-party platforms shall establish a drug quality and safety management body.
	Staffing	Third-party platforms shall be staffed with pharmaceutical professionals to undertake drug quality and safety management work.
	Management system	Third-party platforms shall establish and implement systems in respect of drug quality and safety control, drug information display, prescription review, real-name purchase of prescription drugs, drug delivery, transaction record retention, adverse reactions reporting, and complaint response, among others.
	Publication of operator information	Third-party platforms shall continuously publicize their business license, relevant administrative permit and filing information, contact information, complaint channels, etc., or the links directing to the aforesaid information, at a prominent location on the homepage of their website or the main webpage for their drug business activities.
	Drug information display	Third-party platforms: shall ensure the truthfulness, accuracy, and legality of relevant drug information they display; shall highlight risk warning messages on each prescription drug display webpage, and fully inform consumers of relevant risk warnings before the sale of prescription drugs, which consumers should confirm as a sign of their acknowledgement; shall separately display and prominently label prescription drugs and OTC drugs; shall not directly display the package, label, etc. of prescription drugs on the homepage or start page for prescription drug sales, and shall not display information such as the IFUs of a prescription drug without the approval of the relevant prescription.
	Information submission	(Voluntary requirement) Third-party platforms and drug administrations are encouraged to establish an automated information submission mechanism in such form as an open data interface.
Supervisory obligations	Inspection	Third-party platforms shall strengthen inspections and shall manage drug information displays, prescription reviews, drug sales and delivery, and other practices of online drug distributors using the platform.
	Examination	Third-party platforms shall examine and verify the qualification and quality and safety assurance capacity, etc. of any enterprise applying for doing online drug distribution on the platform, shall establish registration files for such enterprise, and shall verify and update such files at least once in every six months.

Administrative aspects	Specific matter(s) involved	Specific requirement
	Agreement	Third-party platforms shall enter into an agreement with an online drug distributor using the platform to specify both parties' responsibilities for drug quality and safety.
	Information retention	Third-party platforms shall retain information of drug display, transaction records, complaint information, etc. The retention period shall be at least five years, which shall not end within one year after the expiry date of relevant drugs. A third-party platform shall ensure that the relevant materials, information and data are true and complete, and shall provide convenience to online drug distributors using the platform for their preservation of relevant data.
	Inspection and monitoring system	Third-party platforms shall establish an inspection and monitoring system. Where an online drug distributor on the platform is found to have committed any illegal act, the third-party platform shall promptly stop the illegal act and forthwith report to the county-level drug administration at its locality.
	Cessation of services	Where a third-party platform discovers any of the following serious illegal acts, it shall promptly cease the provision of relevant online trading platform services and cease the display of relevant drug information: (1) Selling drugs without qualification; (2) Selling drugs subject to special administration by the State in violation of Article 8 of the *Administrative Measures*; (3) Selling drugs beyond the scope approved for drug distribution; (4) Being ordered by the drug administration to cease sales or having the drug approval license or drug distributor license revoked by the drug administration; (5) Any other serious illegal act. Where a drug approval license is revoked or deregistered pursuant to law, the relevant drug information shall not be displayed.
Obligations to cooperate	Emergency response	In the event of public health emergency or other emergency that poses a serious threat to public health, a third-party platform shall comply with the relevant emergency response provisions of the State, and adopt the corresponding control and response measures pursuant to law.
	Drug recall	Where an MAH recalls drugs pursuant to law, the relevant third-party platform shall actively cooperate in the recall of drugs.
	Regulation and law enforcement actions	Where the drug administration carries out supervision and inspections, case investigations, handling of incidents, etc., the third-party platform concerned shall cooperate in the said actions. Where the drug administration discovers any illegal act of an online drug distributor and requires the third-party platform concerned to take

Administrative aspects	Specific matter(s) involved	Specific requirement
		measures to stop the illegal act, the third-party platform shall promptly perform the relevant obligations; Where the drug administration requires a third-party platform to provide information about distributors on the platform, sales records, pharmaceutical services, tracking information, etc. pursuant to laws and administrative regulations, the third-party platform shall promptly provide such information.

Legal liability and law enforcement

The *Administrative Measures* set forth many legal liabilities and administrative penalties that may be imposed on MAHs, drug distributors, and third-party platforms who violate their required obligations, which are classified into two main categories. The first category comprises standalone penalties created by the *Administrative Measures*, including an order for rectification within a specified time limit and a fine ranging from RMB 10,000 to RMB 200,000, which are imposed, for example, on online drug distributors that do not fulfil their obligations in respect of prescription management, pharmaceutical services, information reporting, drug information display, etc., as well as on third-party platforms that fail to perform obligations regarding the drug quality and safety system, record filing, drug information display, among others. The second category contains legal liabilities cited from the *Drug Administration Law*, with specific penalties determined by the seriousness of relevant circumstances. Parties subject to these liabilities may face heavy fines, revocation of the drug distribution license, and other severe punishments, which will be imposed on, among others, online drug distributors that fail to fulfil their GSP obligations and third-party platforms that fail to perform obligations such as qualification examination, reporting, and ceasing provision of online trading platform services. For example, an online drug distributor that fails to comply with the *Administrative Measures* and other relevant laws and regulations in terms of drug delivery and retention of sales records and other relevant documents may face severe penalties, such as being ordered to make rectification within a specified time limit, receiving a warning, receiving a fine between RMB 100,000 and RMB 2 million, being ordered to suspend manufacturing and business operations to make rectification, and even having its drug distribution license revoked. Meanwhile, the legal representative, key person-in-charge, directly accountable person-in-charge, and other directly accountable personnel of the online drug distributor may also face severe administrative penalties, such as confiscation of their income derived from the company during occurrence of the illegal act plus a fine between 10% and 50% of the income, and a 10-year to permanent ban on their engagement in drug manufacturing and drug distribution activities. In addition to the aforesaid legal liabilities, according to Article 30 of the *Administrative Measures*, where potential safety risks are proved by evidence, the drug administration concerned will, in light of the supervision and inspection findings, issue a warning to the online drug distributor or third-party platform concerned, schedule an interview, order rectification within a specified time limit, suspend the manufacturing, sales, use or import of the drugs concerned, or take other appropriate measures.

Moreover, the current drug administration system in operation should also apply to online drug sales activities. The system is established by relevant provisions in a series of effective laws and regulations,

including but not limited to the *Drug Administration Law*, *Measures for the Administration of Drug Recalls*, *Measures for the Administration of Reporting and Monitoring of Adverse Drug Reactions*, *Good Supply Practice for Pharmaceutical Products*, and even such laws as the *Criminal Law of the People's Republic of China (Amended in 2020)* and the *Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues concerning the Application of Law to Criminal Cases concerning Drug Safety (2022)*. Article 32 of the *Administrative Measures* also provides clarification of this issue, stipulating that where there are provisions in other laws and administrative regulations on punishments for illegal online drug selling behaviors, such provisions shall prevail.

As for law enforcement, under the *Administrative Measures*, provincial drug administrations will be responsible for investigations and punishment of illegal online drug selling practices carried out by third-party platforms, MAHs, and drug wholesalers, while drug administrations at the municipal and county level will be in charge of investigating and punishing illegal acts of online drug retailers. The delegation of law enforcement authority to local-level governments has proved China's robust law enforcement capacity and strength, which should not be underestimated by entities engaging in online drug sales activities in the future.

Conclusion

Through the *Administrative Measures*, China officially gives clear guidance on highly controversial issues in the healthcare e-commerce industry, such as online sales of prescription drugs and third-party platform obligations. It also signifies the government's endorsement for boosting the healthcare e-commerce industry in China and will usher in a new stage of development for the industry. The strict obligations assumed by online drug distributors and third-party platforms under the *Administrative Measures* should not be regarded as a hinderance to industry growth given the truth that, for all industries, without order, long-term and rapid development would be a mere illusion. The *Administrative Measures* specify clear compliance requirements for online drug sales activities, which will effectively enhance the level of services provided by online drug distributors and third-party platforms and guarantee safe drug use by patients, ultimately promoting the orderly, healthy development of the healthcare e-commerce industry. Relevant participants in online drug sales are advised to proactively adapt to the latest regulatory requirements to ensure the legitimacy and compliance of their drug sales practices, which is essential for their continued and lasting development in the industry.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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