

China issued regulation on internet pharmacy: opportunities for Chinese and foreign companies

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Executive summary

A new Chinese regulation, *Administrative Measures for Supervision of Internet Pharmacy*, opens the door wide for the operation of internet pharmacy businesses in China. The Measures, which come into effect on 1 December 2022, permit internet pharmacies and third-party internet platforms hosting internet pharmacies to sell both non-prescription (or over-the-counter (“**OTC**”)) drugs and prescription drugs. Although controlled drugs are not within the scope of the Measures, the new rules present tremendous business opportunities to both local Chinese companies and foreign companies.

This guidance note summarises the key legal requirements for internet pharmacies and third-party platforms hosting internet pharmacies.

Requirements for internet pharmacies

- ✓ Must be either market authorisation holders (or “**MAHs**”) or drug retailers which have the capability to ensure the safety of online sales of drugs.
- ✓ Must operate in accordance with their approved mode and scope of business (Internet pharmacies of MAHs may sell only the drugs covered by their market authorisation).
- ✓ May sell drugs to individual retail customers only if they have retail qualification.
- ✓ May not sell vaccines, blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, and pharmaceutical precursor for toxic chemicals under special control.
- ✓ May not give away drug products to boost drug sales, may not give away drug products for boosting the sale of other goods, or otherwise give away prescription drugs or category A OTC drugs to individual retail customers.
- ✓ Must ensure that the sources of the prescriptions are true and reliable, and must record genuine identities.
- ✓ Should enter into agreements with the relevant providers of electronic prescriptions, strictly comply with the requirements in respect of prescription audit and deployment, and label used electronic prescriptions to avoid reuse of the prescriptions.
- ✓ Must take effective measures to avoid reuse of paper prescriptions.
- ✓ Must establish drug quality, risk management, drug traceability, storage and distribution management, adverse reaction reporting, and complaint and reporting systems.
- ✓ Must also establish online pharmacy service systems, staffed by pharmacists or other pharmaceutical technical experts to carrying out the work of prescription audit and deployment and of guiding rational drug use (The number of pharmacists or other pharmaceutical technical experts should be proper for the relevant business scale).

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- ✓ Should report to the drug regulator the enterprise names, the websites, the Apps, the IP addresses, the domain names, the drug production licenses, the drug business licenses and other information (In case of change, the change should be reported to the regulator within ten working days. If the internet pharmacies are MAHs or drug distributors, the reports should be made to the provincial level regulator, but in the case of retail internet pharmacies, the reports should be made to the city/county level regulator).
- ✓ Must display on the home pages of their websites their drug production or business license information; must display information on the qualifications of their pharmacists or other pharmaceutical technical experts (In case of change of information, the information should be updated within ten working days).
- ✓ Are liable for the quality and safety of drug distribution (The volume of the drugs, transportation distance, transportation time, temperature and humidity requirements, and other factors determine the choices for the appropriate transportation tools, facilities and equipment. The drugs for distribution should be placed in a separate location and clearly marked to ensure regulatory compliance and full traceability).
- ✓ If third parties are to handle distribution tasks, should audit the quality management system of the third parties, enter into agreements with the third parties covering drug quality responsibilities, operating procedures and other issues, and supervise the distribution work of the third parties (The regulator, National Medicine Products Administration, is likely to issue specific requirements on distribution soon).
- ✓ Must issue receipts (The receipts may be in digital form, and the smallest sales units of the drug sales records should be clearly retained to ensure traceability).
- ✓ Should keep the supplier qualification documents, electronic transaction records and other documents; if prescription drugs are sold, should keep records of the prescriptions, online pharmacy services, and other documents (Relevant records should be kept for no less than five years, and in any event not less than one year after the expiry of the relevant drug product).
- ✓ Should take appropriate risk control measures and promptly in the home or main pages publish relevant information in respect of drug products with quality problems or safety risks.

Requirements for third-party platforms hosting internet pharmacies

- ✓ Should verify the electronic prescription providers and enter into agreements with the providers.
- ✓ Should establish drug quality and safety management systems staffed with pharmaceutical technical experts to undertake drug quality and safety management, and should establish and implement management systems for drug quality and safety, drug information display, prescription audit, prescription drugs purchasing in actual names of individuals, drug delivery, transaction record keeping, adverse reaction reporting, and handling of complaints and reporting.
- ✓ Should thoroughly inspect the drug information displays, the prescription audit, the drug sales and distribution and other activities of the internet pharmacies, and urge them to be in strict compliance.
- ✓ Must record the enterprise names, legal representatives, unified social credit codes, website names, domain names and other information to the provincial level regulator which would publish the information.
- ✓ Must prominently display on their home or main pages their business licenses, relevant licenses and recordals, contact information, and modes of lodging complaints and filing reports, or the logos for the links to the above information.
- ✓ Must review the qualifications and quality and safety assurance capabilities of the internet pharmacies, and establish registration files of them which must be updated at least once every six months to ensure that the internet pharmacies meet the statutory requirements.
- ✓ Should enter into agreements with the internet pharmacies to clarify the responsibility for drug quality and safety.
- ✓ Should keep records of drug display, transaction records, complaints and reporting and other information, for not less than five years, and not less than one year after the expiry date of the relevant drug; should ensure that the information is true and complete, and should facilitate the internet pharmacies keeping their own records.
- ✓ Should establish systems of inspection and monitoring of the internet pharmacies, so that any contravention of the law is promptly stopped and reported to the local county-level regulator.
- ✓ Must stop transactions and display of drug-related information if any of the following non-compliance is found:
 - a) lacking qualification for selling drugs
 - b) sale of controlled substances
 - c) sale of drugs outside of the approved scope of the relevant licenses
 - d) having engaged in illegal activities and being ordered to stop sales or having licenses revoked
 - e) other serious violations of the law

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- ✓ If the market authorisation for the relevant drug product is revoked, must stop displaying information on the drug product.
- ✓ Should promptly cooperate with the regulator's inspections and investigations, including executing injunctions and providing information and documents.
- ✓ Are to automate submission of data to the regulator.

Requirements for both internet pharmacies and third-party platforms hosting internet pharmacies

- ✓ Must not feature untrue, inaccurate or illegal drug information.
- ✓ Must highlight at the bottom of each webpage "prescription drugs must be purchased and used under the direction of a pharmacist" and other warnings, if prescription drugs would be sold (Before the sale of prescription drugs, the relevant risks should be fully informed to and acknowledged by the consumers).
- ✓ Should separately display and prominently label prescription drugs and non-prescription drugs to distinguish them.
- ✓ Must not on the main or home pages for prescription drugs directly and publicly display prescription drug information such as prescription drug packaging and labeling (Before completing prescription audit, prescription drug information should not be disclosed and services should not be provided).
- ✓ Must comply with national regulators on emergency responses during public health crisis or other serious threats to public health.
- ✓ Must cooperate when MAHs proceed with drug recalls.

Opportunities and challenges

Research conducted by Frost & Sullivan shows that there are huge opportunities in China for internet pharmacies. Internet pharmacies account for over 30% of the total retail sales in US, whereas the figure for China is only 1.5%. The timing is particularly good as over half of the Chinese population are internet users and regularly shop online and China is experiencing a massive increase in demand for health care goods and services. By expressly allowing the operation of internet pharmacies and internet platforms for hosting internet pharmacies as well as allowing internet pharmacies to sell not just OTCs but also prescription drugs, the new Measures will fuel the expansion of internet pharmacies in China. Last but not least, internet pharmacies require only ICP (Internet Content Provider) recordals rather than ICP licenses, allowing foreign companies to also take advantage of the new Measures to venture into China's internet pharmacy opportunities.

A report on the Chinese internet pharmacy market by ASOP Global and LegitScript finds that 57% of online drug sellers are operating illegally with respect to Chinese law and regulation. Buying pharmaceuticals online illegally can expose patients to tremendous risk. The Chinese government has made huge strides in its efforts to create a robust system to monitor and take down illegal internet pharmacies. The new Measures are another big step to protect the safety of patients and the public at large. Local Chinese companies and foreign companies that demonstrate leadership in navigating and implementing the new legal requirements will be well-positioned to capitalise on the tremendous business opportunities made available by the new Measures.

Let's talk

For a deeper discussion of how this impacts your business, please contact us.

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