Pharmaceutical Advertising 2021

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China

Trends and Developments

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East & Concord Partners has a well-earned reputation as one of the largest and most comprehensive law firms in China. With more than 400 legal professionals, the firm advises multinational companies, publicly listed companies, privately owned companies, state-owned enterprises, foreign invested companies, government offices and public institutions on a wide range of areas. Headquartered in Beijing, the firm has seven offices strategically located throughout China. The firm has also established extensive co-operation with many well-known international law firms so as to satisfy the development need of the economic globalisation. With more than 20 years of experience, the firm has gained a leading position and earned clients' trust and recognition in areas including banking and finance, mergers and acquisitions, anti-dumping and anti-subsidy, pharmaceutical and healthcare, infrastructure and project financing, intellectual property, government legal affairs, cybersecurity and data protection, dispute resolution.

Recent Legislative and Regulatory Developments and Trends

China's pharmaceutical industry has developed rapidly in recent years and past drug laws and regulations can no longer effectively administer the fast-changing pharmaceutical industry. Therefore, at the end of August 2019, the newly revised Drug Administration Law of the People's Republic of China ("Drug Administration Law") was promulgated, and it came into effect on 1 December 2019. The newly revised Drug Administration Law is the first comprehensive overhaul in 18 years since its revision in 2001.

The new law stipulated the nationwide adoption of the drug marketing authorisation holder system, introduced implied licence for the clinical trial approval, replaced the approval system for setting up clinical trial entity with record filing, preliminarily established the sympathetic medication system,

improved the drug traceability, and increased the penalties for violations. It also addressed hot issues in the pharmaceutical industry, and developed those effective practices and experiences of the recent pharmaceutical, medical and health reforms as legal requirements.

Supporting implementation

After the revision of the Drug Administration Law, regarded as the basic law in the field of drug regulation, a series of important supporting implementation rules were released in 2020, which included:

- Administrative Measures for Drug Registration;
- Measures for the Supervision and Administration of Drug Production;
- Regulations for Quality Management of Drug Clinical Trials;
- Working Procedures for Breakthrough Therapeutic Drug Review (Trial);
- Guidelines for Commissioned Drug Production and Quality Agreements;
- Clinical Technical Requirements for Overseas Marketed and Domestic Un-marketed Drugs; and
- Administrative Measures for Drug Post-Marketing Change (Trial).

Pharmaceutical advertising

Regarding pharmaceutical advertising, at the end of December 2019, the State Administration for Market Regulation (SAMR) issued the Interim Measures for the Administration of Review of Advertisements on Drugs, Medical Devices, Dietary Supplements and Formula Foods for Special Medical Purposes (the "Interim Measures"). Prior to the promulgation of the Interim Measures, the regulation and supervision of pharmaceuticals largely relied on dispersed regulations promulgated by relevant regulatory bodies. Taking effect on 1 March 2020, the Interim Measures replaced and abolished five regulations earlier promulgated by

the State Administration for Industry and Commerce, Food and Drug Administration and other departments. These abolished regulations are:

- the Measures for the Review of Pharmaceutical Advertisements;
- the Standards for the Review of Pharmaceutical Advertisements;
- the Measures for the Review of Medical Device Advertisements;
- the Standards for the Review and Release of Medical Device Advertisements; and
- the Interim Regulations on the Release of Food Advertisements.

The Interim Measures uniformly regulate the advertising of drugs, medical devices, dietary supplements and formula foods for special medical purposes (commonly known as "three products and one device"), while higher-level legal guidance can be found in the Advertising Law, Drug Administration Law and its implementing regulations, Food Safety Law and its implementing regulations, as well as Regulations on the Supervision and Administration of Medical Devices.

In drug promotion activities, non-compliance issues such as commercial bribery, sales with kickbacks and issuing false VAT invoices conducted by CSOs and medical representatives have always been the focus of supervision. In order to regulate the academic drug promotion activities and facilitate the implementation of the drug marketing authorisation holder system, on 22 September 2020 the State Drug Administration issued the Administrative Measures for the Recordation of Medical Representatives (Trial) ("Measures for the Recordation of Medical Representatives"), which redefined the role of medical representatives and made clear the compliance requirements imposed on medical representatives in their work performance.

Legislation

In the field of legislation, China currently has no single law or regulation governing pharmaceutical advertising and promotion. In the field of law enforcement, multiple departments are involved and co-ordinated for the supervision, which include market regulatory agencies, drug regulatory agencies, health commissions and other relevant government agencies.

Compliance Requirements Regarding Academic Promotion Activities by Medical Representatives

According to the newly promulgated Measures for the Recordation of Medical Representatives, medical representatives shall not engage in the following activities:

- conduct activities such as academic promotion without filing record;
- conduct academic promotion and other activities without the consent of medical institutions;
- conduct drug sales and other sales activities such as collecting payments and processing sales receipts;
- participate in the counting of drug prescriptions issued by individual doctors;
- directly provide donations, funding or sponsorship to internal departments or individuals of medical institutions;
- mislead doctors to use medicines, exaggerate or mislead curative effects, conceal known adverse side effect information of medicines or conceal adverse side effect information feedback from doctors; and
- other interventions or actions that affect the clinical rational use of medicines.

Medical representatives should obtain the consent of the medical institution to carry out academic promotion and other activities in the medical institution, and

abide by the relevant regulations of the health department.

Marketing Authorization Holder (MAH), as obligated to file for the medical representative, shall submit the relevant filing materials of the medical representative on the filing platform. The MAH shall strictly perform its management responsibilities for the medical representatives employed or authorised, and publicise the information of the medical representatives employed or authorised on its website. If the MAH does not have a website, it should publicise the information on the website of relevant industry association.

Trade Mark Issues Related to Pharmaceutical Advertising

The Interim Measures that came into effect on 1 March 2020 no longer require that "registered trademarks should not be used in drug advertisements to replace drug names for publicity". Therefore, drug trade marks have a bigger role to play in advertising.

It is easier for both consumers and medical and pharmacy professionals to remember and restate trade mark than generic drug name, and trade marks help distinguish sources of drugs. Therefore, trade marks are important in pharmaceutical advertising, and it is necessary to consider trade marks when making advertisements. In this regard the following issues need to be considered.

Concurrent use of foreign language trade marks and Chinese trade marks

For drugs imported into the Chinese market from abroad, it is recommended to have a Chinese trade mark. The use of both Chinese trade mark and foreign language trade mark in drug advertisement can better promote sales in the

Chinese market. This is also the common practice of major foreign pharmaceutical companies in China.

Create a good Chinese trade mark (trade name) for the drug

Foreign pharmaceutical companies usually translate their foreign language trade marks into Chinese based on its pronunciation. For example, Eli Lilly's antibiotic cefaclor's English trade mark is "Ceclor", and its Chinese trade mark is "xikelao".

When making translation, it is obvious that besides pronunciation, one should also consider the meaning of the Chinese characters and whether they are easy to write and remember. It is better for a trade mark not to exceed more than four Chinese characters.

The specific work in this area is advised to be undertaken by a local branch/subsidiary in China, or entrusted to a local consulting company.

Prepare for the risk of possible cancellation of registered trade marks

According to China's trade mark law, if a trade mark has not been used for three consecutive years after registration, anyone can request cancellation of the registered trade mark. Therefore, the registrant of a drug trade mark should pay special attention to timely collection of relevant evidence proving the use of the trade mark in the process of clinical trials and application for approval. If appropriate, re-application for the same trade mark is also an option so as to decrease the risk of losing the trade mark.

Trade marks relating to prescription drugs

It is worth noting that the trade marks must not be used in media other than medical and pharmacy professional publications for advertising purpose, nor may they be used to title various sponsor activities for advertising.

The Broader Trend of Identifying Internet Pharmaceutical Advertising

Internet drug advertising, besides meeting the content and format requirements of general drug advertising, should also comply with the Interim Measures for the Administration of Internet Advertising and Administrative Measures for Internet Drug Information Services.

To publish on internet, the advertisement must be reviewed and approved by the food and drug regulatory authorities, and obtain an Internet Drug Information License. The advertisement shall display the word "advertisement" and the review approval number. Promotional articles and videos on medical online platforms specifying drug manufacturers and illustrating drug efficacy will be deemed to constitute drug advertisements. In addition, internet websites must not publish information on preparations of medical institutions or special drugs such as narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs, as well as advertisement for prescription drugs.

In practice, law enforcement agencies identify internet drug advertising in an increasingly broader scope, making room for further clarification. For example, in 2018, a Mr Cao, who promoted a certain medicine by claiming its efficacy in his WeChat (a Chinese massaging and social media APP) posts and WeChat groups, was punished by relevant authorities for using the internet to advertise drugs. This case roused some controversy, as some believe that WeChat groups or WeChat Moments belong to private domain, and the release of the drug information is for communicating with friends. Therefore, identifying such behaviour as drug advertisements will expand the scope of drug advertising and lead to excessive supervision.

Despite this controversy, the law enforcement agencies still have a broader understanding and identification of internet drug advertising. Under current policy and regulatory environment, it is advisable for internet drug advertisement publishers and operators to elevate compliance standards.

Advertising Supervision of Cross-border E-commerce Imported Drugs

Since 2013, a series of favourable policies have been introduced in China to support cross-border e-commerce. The pilot cities for cross-border e-commerce services have expanded from the initial five cities of Shanghai, Chongqing, Hangzhou, Ningbo and Zhengzhou to 105 cities and areas. According to the Notice on Improving the Supervision of Cross-border E-commerce Retail Imports issued by the Ministry of Commerce and five other governmental departments at the end of November 2018 and implemented on 1 January 2019, cross-border e-commerce retail imports refer to Chinese domestic consumer purchase goods from overseas through third-party cross-border e-commerce platform, and goods received from bonded warehouse or direct delivery.

The cross-border e-commerce retail imported goods are regulated as imported goods for personal use, so the requirements imposed on first-time imports such as approval licence, registration or filing is not applicable. Before the end of 2019, drugs were not included in the cross-border e-commerce imports list. At the end of December 2019, 13 departments including the General Administration of Customs, the State Adminiatration for Market Regulation (SAMR) and the National Medical Products Administration jointly issued the Cross-border E-commerce Retail Import Commodities List (2019 Edition) (hereunder "2019 List"), which was further expanded and for the first time had drugs included.

According to the 2019 List, medical products such as Chinese medicine wine, cooling oil, adhesive plaster and medical adhesive are allowed to enter China through cross-border e-commerce. Currently, some products of pharmaceutical companies such as Hisamitsu Pharmaceutical of Japan and Hong Kong Ching On Tong Medicine Factory have been successfully introduced to the Chinese market through the cross-border e-commerce channel. Under supervision of National Medical Products Administration (NMPA) and other related agencies, a pilot program was launched in Beijing at the end of December 2019 to further expand the scope of and streamline the process for medical products via this pattern.

Selling drugs through e-commerce platforms

When selling drugs through e-commerce platforms, it is inevitable to publish promotional information such as drug efficacy and drug ingredients, which constitutes the publication of drug advertisements according to the Interim Measures. Therefore, before the publication, relevant materials such as drug registration certificate should be submitted in order for the advertisement to be reviewed. However, since sales through cross-border e-commerce platform requires no registration approval, it may not be possible to submit these materials required for applying for drug advertisement review.

Currently no clear rules exist on whether the Interim Measures are applicable to the publication of drug advertisements on cross-border e-commerce platforms, thus there is a discrepancy between the regulatory requirements for cross-border e-commerce imported drugs and the current drug advertising regulations. From the publicly available information, no cases have yet been reported that publishing advertisement of imported retail drug being penalised on cross-border e-commerce platform.

As drug imports by cross-border e-commerce is still in the pilot stage in China, the above-mentioned regulation discrepancy is hopefully to be clarified and perfected by the relevant government departments in their future supervision and practice. It is recommended that interested parties pay continuous attention to the development of this issue.

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