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Pharmaceutical Advertising 2022

China: Law & Practice
Alan Zhou, Xuchun Huang, Xuan He and Qiuyan Dong
Global Law Office

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CHINA

Law and Practice

Contributed by:
Alan Zhou, Xuchun Huang, Xuan He and Qiuyan Dong
***Global Law Office** see p.23*

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1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Under the PRC legal system, advertising on medicines is subject to the following regulations.

- The Advertising Law serves as the foundation and was promulgated to regulate all types of advertising. It contains general principles and special provisions for pharmaceutical advertising. Regulators issue detailed measures for drug advertisements under the Advertising Law.
- The Drug Administration Law regulates the whole life cycle of a drug, including its advertising and promotional activities.
- The Anti-Unfair Competition Law prohibits unfair competition activities, including fraud, misleading promotions and commercial bribery. This general law applies to the pharmaceutical industry.

The major laws and regulations are:

- the Advertising Law (latest revisions effective in 2021);
- the Anti-Unfair Competition Law (latest revisions effective in 2019);
- the Interim Provisions on Banning Commercial Bribery;
- the Law on the Protection of Consumer Rights and Interests (latest revisions effective in 2014);
- the Drug Administration Law (latest revisions effective in 2019);
- the Regulations on the Control of Advertisements;
- the Implementing Regulations of the Drug Administration Law (latest revisions effective in 2019);
- the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes ("Administrative Measures for Review of Drug Advertisements");
- the Administrative Provisions on Pharmaceutical Directions and Labels;
- the Interim Measures for the Administration of Internet Advertising;
- the Administrative Measures for Online Drug Information Services (latest revisions effective in 2017);
- the Administrative Measures for Record-Filing of Medical Representatives (for Trial Implementation) ("Administrative Measures for Medical Representatives");
- the Administrative Measures for the Receipt of Public Welfare Donations by Health and Family Planning Agencies (for Trial Implementation) ("Administrative Measures for the Receipt of Public Welfare Donations"); and
- the Nine Criteria for the Incorrupt Practice of Staff of Medical Institutions ("Nine Criteria").

In addition to the above laws and regulations, industrial associations and institutions also have their own codes of conduct to regulate members' promotion and advertising activities. These are normally referred to as "industry benchmarks". The major self-regulatory codes for medicine advertising include:

- the R&D-based Pharmaceutical Association Committee Code of Practice (the "RDPAC Code" – latest revisions effective in 2019) – the RDPAC is a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA);
- the Code of Ethics for Pharmaceutical Enterprises in China;
- the Code of Ethics for Licensed Doctors in China;

- the Code of Professional Ethics for Licensed Pharmacists in China;
- the Guidance for Application of the Code of Professional Ethics for Licensed Pharmacists in China; and
- the Draft Code of Conduct for Chinese Medical Representatives (which has not yet been officially promulgated).

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes generally apply to the members of the relevant associations, including member organisations and/or individual members.

For example, the RDPAC Code applies to RDPAC's member companies (although the annotation of the RDPAC Code further notes that the Code covers all relevant company employees as well as subcontractors that carry out tasks on behalf of the company). The Code of Ethics for Pharmaceutical Enterprises in China in principle applies to its member organisations, including RDPAC and other associations.

Other self-regulatory codes apply primarily to individual members. The Code of Ethics for Licensed Doctors in China applies to licensed physicians, licensed assistant physicians, scholars and health administrative personnel, as well as healthcare institutions and certain other organisations. The Code of Professional Ethics for Licensed Pharmacists in China and the Guidance for Application of the Code of Professional Ethics for Licensed Pharmacists in China apply to all licensed pharmacists and other pharmaceutical technicians who temporarily perform the duties of licensed pharmacists.

None of these self-regulatory codes are mandatory. They are contractual in nature and reflect a certain level of industry consensus among a large group of market players. Some of these self-regulatory codes may reflect higher standards than laws and regulations. Others elaborate on issues with respect to which the law is silent, such as the scope of communications allowed with respect to off-label use of medicines and the level of substantiation required for promotional purposes. Certain self-regulatory codes, such as the RDPAC Code, also provide an alternative dispute resolution programme for their members, including panel reviews, mediation and sanctions.

2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

2.1 Definition of Advertising

The definition of advertising under the Advertising Law is broad. Advertising appears to cover any commercial activities whereby business operators or service providers directly or indirectly introduce and recommend products or services they are marketing by using certain forms of media.

The former State Administration for Industry and Commerce (SAIC), now reformed into the State Administration for Market Regulation (SAMR), and the Legislative Affairs Commission of the Standing Committee of the National People's Congress, summarise the characteristics of advertisements in their interpretations of the Advertising Law. They define an advertisement as a commercial activity that:

- is transferred through certain media (including both traditional media and new media), rather than directly between individuals or groups of individuals (eg, speech to specific audiences in a conference; one-to-one oral introduction to patients in a pharmacy);

- points to a specific commodity or service of a business operator as the identifiable beneficiary (the advertiser); and
- is for-profit and promotional purpose, ie, its purpose is to influence the public's attitude towards the commodities or services.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

For the purposes of this section, "information" in the narrow sense refers to the factual description and introduction of products and services. Under the Law on the Protection of Consumer Rights and Interests, consumers are entitled to know the correct information about the products and services, such as the price, place and date of manufacture, and term of validity.

Advertising, however, is about making recommendations for products or services. Its main purpose is to generate a positive attitude in the audience towards the products or services being presented.

Law Enforcement Perspective on Advertising

From a law enforcement perspective, the "information" part of an advertisement is not subject to legal scrutiny under the Advertising Law. For example, when reviewing the content of an advertisement, the State Administration for Market Regulation tends to carve out the information that is required by laws and regulations to be provided to consumers, and will only scrutinise the rest of the advertisement as a "commercial advertisement".

Qualifying Events as Advertising

Whether disease awareness campaigns may qualify as advertising depends on whether the event is promotional in nature. If a disease awareness campaign simply provides general disease awareness information, then it is not likely to be regarded as advertising. If the information provided can be either individually or collectively viewed as pointing to a specific product, such information may be considered "drug information" and the campaign may be considered promotional in nature and may fall into the scope of advertising. Under the Administrative Measures for Review of Drug Advertisements, "drug information" may include drug names, diseases to which the drugs are applicable (functions and indications) or other drug-related content.

A disease awareness campaign may be aimed at healthcare professionals, patients or the general public, and there is no legal difference based on the type of audience. In practice, however, if a disease awareness campaign targets the general public, product-specific information is generally not allowed to be mentioned; otherwise, law enforcement is more likely to regard the campaign as advertising. Other compliance requirements are discussed in **7.4 Provision of Disease Awareness Information to Patients Online**.

2.3 Restrictions on Press Releases regarding Medicines

The law in China does not prohibit press releases regarding medicines, but promotion of medicines in the disguised form of press releases without prior regulatory approval is restricted. In practice, press releases are allowed only if they contain a strictly factual description of the medicine, such as the completion of clinical studies, the obtainment of relevant market approval, or the launch of a new product in a new jurisdiction. If the content of the press release exceeds such limited scope and includes elements of advertising/promotion, then it may fall into the scope of advertising and become subject to the Advertising Law.

There are generally no differences between press releases available in the specialised trade press and press releases in mainstream media.

2.4 Comparative Advertising for Medicines

The Advertising Law explicitly prohibits comparative advertising for medicines with respect to the medicine's efficacy and safety.

Comparison may nevertheless be allowed if the underlying activity is considered to be outside the scope of advertising. Under the RDPAC Code, comparison with other pharmaceutical products is generally allowed if the comparison is based on relevant and comparable aspects of the products and is capable of substantiation. Comparative claims, where possible, must not be misleading.

3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

PRC laws do not expressly prohibit the provision of information on unauthorised medicines or unauthorised indications but this is nonetheless prohibited under the Advertising Laws if the sharing or provision of such information constitutes advertising. Under the Advertising Laws:

- almost all drug advertisements are subject to the pre-approval of the local counterparts of the National Medical Products Administration (NMPA; formerly known as China Food and Drug Administration) before release; and
- only advertisements of authorised medicines can be approved by the local NMPA (advertising may not refer to anything that is inconsistent with the medicine's instructions as approved by the authorities).

Therefore, where there is a lack of market authorisation, advertising on unauthorised drugs is unlikely to be approved and permitted by the local NMPA.

As mentioned previously, the definition and concept of "advertising" is vague and could have broad scope. In practice, pharmaceutical companies in China are cautious in providing information on unauthorised medicines or unauthorised indications, to avoid what could constitute illegal advertising. Benchmark practice discourages this activity. For example, the RDPAC Code states that no pharmaceutical product may be promoted for use in China until the requisite marketing authorisation for such use has been given by the NMPA.

Also under the RDPAC Code, in one-on-one visits with healthcare professionals, medical representatives are not allowed to provide information on unauthorised medicines or unauthorised indications without the supervision of medical experts (see **3.3 Provision of Information to Healthcare Professionals**).

3.2 Provision of Information during a Scientific Conference

There is no direct legal prohibition against providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals.

According to the RDPAC Code, off-label promotion is prohibited, but the prohibition is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. Also, the Code is not intended to restrict the full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigative findings in scientific or lay communications media and at scientific conferences.

Therefore, information on unauthorised medicines or unauthorised indications is generally allowed if it is confined to scientific exchanges and is not promotional in nature. However, if the information is promotional in nature, law enforcement may easily view it as prohibited advertising, especially if there is a large audience.

3.3 Provision of Information to Healthcare Professionals

Under Administrative Measures for Medical Representatives, medical representatives are prohibited from misleading doctors on the usage of drugs, exaggerating or misleading the curative effect, concealing known information on adverse drug reaction and the information on adverse drug reaction reported by healthcare professionals. The pharmaceutical company as the marketing authorisation holderof the medicines is required to promptly correct any aforesaid wrongdoing by the medical representatives.

Therefore, when medical representatives are discussing scientific information on unauthorised medicines or indications with healthcare professionals, such information must conform with the aforementioned requirements. It is also advisable to have the competent department of the company review such information in advance, to ensure the accuracy of the contents. The RDPAC Code states that pre-approval of off-label communication with healthcare professionals, whether in oral or written form, should be conducted by or under the supervision of medical experts instead of personnel with commercial functions.

3.4 Provision of Information to Healthcare Institutions

Public healthcare institutions in China generally do not procure drugs on their own initiative. Procurement is organised by the government through bidding performed on bidding platforms (including the recent volume-based procurement). Thus, public healthcare institutions usually do not have direct access to information on unauthorised medicines or unauthorised indications for the purposes of preparing budgets. Conversely, the relevant government departments involved in public bidding, such as the NMPA, the National Health Commission and the National Healthcare Security Administration, may access such information.

3.5 Publication of Compassionate Use Programmes

The concept of compassionate use programmes is only generally mentioned in the Drug Administration Law as a form of early access for patients. The draft measures regulating the use of medicines in extended clinical trials for compassionate use have not yet been promulgated.

PRC laws do not expressly prohibit the publication of compassionate use programmes, however, if information on a programme that is released to the public cannot be proved necessary for the purpose of an expanded clinical trial for compassionate use, it might constitute advertising, which is not allowed to provide information on unauthorised medicines or unauthorised indications, as discussed in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Not all categories of medicines can be advertised to the general public. The Administrative Measures for Review of Drug Advertisements strictly prohibit advertising for several special categories of medicines such as:

- narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs;
- pharmaceutical precursor chemicals and medicines for drug rehabilitation treatment;
- drugs specially needed by the military and preparations made by military medical institutions;
- pharmaceutical preparations made by healthcare institutions; and
- drugs prohibited from production, sale or use by law.

Advertising of all other prescription-only medicines is only permitted in professional pharmaceutical or medical journals jointly designated by the Ministry of Health and the NMPA. No prescription-only medicines can be advertised in the mass media or promoted in any other manner targeting the general public. Specifically, the Administrative Measures for Review of Drug Advertisements forbid the use of the names of prescription-only medicines to sponsor/title various activities for advertising, and also prohibit the use of any trade mark or trade name identical to the name of a prescription drug to publish any advertisement in a disguised manner in any media other than professional pharmaceutical or medical journals, or the use of such trade mark or trade name in the title of any activity for advertising.

Therefore, only over-the-counter medicines may be advertised to the general public, and such advertising must comply with substantive and procedural legal requirements. Under the Advertising Law, the Drug Administration Law and the Administrative Measures for Review of Drug Advertisements, advertisements for medicines are subject to review and approval from the drug regulatory department of the provincial-level government where the company is located (ie, the local NMPA), which is more fully discussed in **6.1 Requirements for Prior Notification/ Authorisation**.

Format and Medium of Medicine Advertising

There are also certain restrictions with respect to the format and medium of medicine-specific advertising. For example, medicine-specific advertising cannot be disguised as programmes introducing knowledge about health and well-being and such advertising may not be published in media that targets minors.

Medicine-specific advertising must comply with all the requirements that apply to advertising in general. For example, the Advertising Law states that advertising cannot contain national symbols, words such as “national”, “supreme”, or “best”, or obscene, violent or discriminatory language. Statistical citations and patent references must be true and accurate. In addition, advertising cannot degrade the goods and services of others.

Certain restrictions also apply to the format and medium of advertising in general. All advertisements published through mass media must be prominently marked as “advertisement”, and a distinction must be made by the advertiser between advertisement and non-advertisement information, so as not to mislead consumers. For example, advertising cannot be broadcast or published in the form of news reports.

Outdoor advertisements cannot be placed on military facilities or traffic signs, or in certain areas controlled by national institutions, cultural heritage reserves and scenic spots. Without prior consent or request, advertisements cannot be sent to people’s residences or placed on transportation devices, or sent via electronic messages. Electronic messages must contain the sender’s identity, contact information and ways to unsubscribe from the messages.

Endorsements

Under the Advertising Law, no endorsement can be made in advertising for medicines, not even

by a healthcare professional. The Administrative Measures for Review of Drug Advertisements further prohibit the use of the names or images of experts, scholars, physicians, pharmacists and clinical nutritionists as a recommendation or endorsement.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

As a general principle, all advertisements must be true, lawful and must not contain any false or misleading content. Advertisers are responsible for the veracity and legitimacy of the content.

As advertising of prescription-only medicines is either prohibited entirely or only permitted in professional pharmaceutical or medical journals jointly designated by the Ministry of Health and the NMPA, advertising directed at the general public can only be for over-the-counter medicines.

Under the Advertising Law and the Administrative Measures for Review of Drug Advertisements, pharmaceutical advertising of a drug must include contraindications, adverse reactions and the drug advertisement approval number. For over-the-counter medicines, the advertisement should clearly use the abbreviation "OTC" and the following language: "Please follow the instructions for the drug or purchase and use it under the guidance of a pharmacist". For required content, fonts and colours must be clearly visible and legible. When released on TV, movies, the internet and display screens, such content must be continuously displayed in the advertisement (rather than for only five seconds as required by previous regulations).

Also, pharmaceutical advertising cannot contain: assertions or guarantees of efficacy and safety; specifics about the cure rate or efficacy rate; comparisons with other drugs; endorsement by a spokesperson; or anything else that is inconsistent with the approved instructions.

Items Prohibited in Pharmaceutical Advertising

The Administrative Measures for Review of Drug Advertisements prohibit all of the following in pharmaceutical advertising:

1) either openly using or using in disguised form the names or images of state organs, functionaries of state organs, military entities or military personnel, and the use of military equipment, facilities, etc for advertising purposes;

2) using the names or images of research institutes, academic institutions, industry associations or experts, scholars, physicians, pharmacists, clinical nutritionists, patients and others for recommendation or as endorsement;

3) using express or implied statements, contrary to valid science, that the product can cure all diseases, adapt to all symptoms and all groups of people, or that it is necessary for normal life and disease treatment;

4) including content that induces unnecessary anxiety and fear among the public about their health status and the diseases they suffer from, or that lead to public misunderstanding that they will suffer from a certain disease or the disease will worsen if they do not use the product;

5) the use of words and expressions like "safe", "safe, non-toxic and with no side effects" and "minor toxic side effects"; or expressed or implied statements that the ingredients are "natural", thus ensuring safety;

6) including content that induces purchase, such as "hot sales", "rush to buy or use on a trial basis", "family necessities", "free treatment" and "free gifts"; comprehensive evaluation such

as "evaluation, ranking, recommendation, designation, selection and awards"; or content such as "refund if not effective" and "insurance with insurance companies" that encourages consumers to arbitrarily and excessively use drugs, health food and formula food for special medicinal purposes; or

7) including content such as the name, address, contact information, service items and service methods of the medical institution, as well as such medical services as free treatment, medical consultation hotline, special out-patient service, etc.

Bullet points two to five might also trigger false advertising claims and subject the advertiser to strict penalties, as discussed in **11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe**.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Patient organisations registered as formal associations are uncommon in China. Therefore, the law in China is silent on interactions between patient organisations and the industry, such as, whether companies can sponsor patient organisations' meetings.

Interactions between patients and the industry are restricted. Although the RDPAC Code encourages companies to make clinical trial information more publicly available to patients as well as to healthcare professionals, in practice, if a patient makes an enquiry to a pharmaceutical company about its drugs and indications, the company can only provide a consultation response through its medical affairs team and the information must be consistent with the information in the instructions already approved by the authorities.

Regarding the direct distribution of drugs to patients under the Provisions for Supervision of Drug Distribution, prescription-only medicines and a sub-category of over-the-counter medicines are generally prohibited from being offered to patients for free, as in "buy one, get one free", or other quantity-related promotions. Donating prescription-only medicines to patients in a charity activity, such as donations made under patient aid programmes (PAPs), is not explicitly regulated under current Chinese laws and regulations. However, it is widely understood that PAPs are, by nature, a charity activity that aims to provide drug assistance to financially burdened patients seeking to obtain drugs that are critical to their lives. Offering free prescription-only medicines is not prohibited under charitable PAPs conducted by qualified persons.

5. ADVERTISING TO HEALTHCARE PROFESSIONALS

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Both over-the-counter medicines and prescription-only medicines can be advertised to healthcare professionals (other than the categories for which advertising is entirely prohibited under the Advertising Law and the Administrative Measures for Review of Drug Advertisements). For prescription-only medicines that can only be advertised to healthcare professionals, the advertising should be marked "This advertisement is for medical and pharmaceutical professionals only" in a prominent position.

Otherwise, the requirements and prohibitions for advertising directed at healthcare professionals are similar to the requirements and prohibitions for advertising directed at the general public. The scope of information is subject to the same

Advertising Law and Administrative Measures for Review of Drug Advertisements that were discussed in **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

Some of the prohibitions for advertising directed at the general public may not be applicable to advertising directed at healthcare professionals, such as the one stating that medicine advertisements should not induce unnecessary anxiety and fear among the public about their health status and the diseases they suffer from, or that lead the public to believe they will suffer from a certain disease or the disease will worsen if they do not use the products.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under the Advertising Law and the Drug Administration Law, drug advertising may not refer to anything that is inconsistent with the medicine's instructions (similar to the summary of product characteristics in Europe) as approved by the authorities. The Administrative Measures for Review of Drug Advertisements specify that, where a drug advertisement involves a drug name, indications or major functions, pharmacological effects, etc, it may not go beyond the scope of approved instructions. Therefore, advertising may not refer to data on file or other clinical studies that are not already included in the instructions.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Information on combination products needs to be included in a medicine's instructions (similar to the summary of product characteristics in Europe) under PRC law on the grounds that all usage information is legally required to be specified in a medicine's instructions. Therefore, in principle, there should be no information on combination products that is not included in the medicine's instructions, and advertising of such information is prohibited in that it is inconsistent with the medicine's instruction, as discussed in **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

The law in China does not prohibit companies from providing reprints of journal articles to healthcare professionals. Although generally allowed under the RDPAC Code, quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable regulations or administrative rules, in which case, it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

5.5 Medical Science Liaisons

Medical science liaison (MSL) is not a legal term under PRC law. However, medical representatives as professional personnel may assume some similar functions to those of MSLs as defined in the Administrative Measures for Medical Representatives, such as transmitting relevant information about medicines to healthcare professionals, assisting healthcare professionals in the rational use of the medicines, collecting and giving feedback on the clinical use of drugs and information on the demands of hospitals. The marketing authorisation holder is required to file the information of its medical representatives and the medical representatives from contract sales organisations.

Although the law does not expressly prohibit medical representatives from discussing scientific information on unauthorised medicines or indications with healthcare professionals, according to the Administrative Measures for Medical Representatives, medical representatives are prohibited from undertaking drug sales targets, misleading doctors on the usage of drugs, exaggerating or giving misleading information on the curative effect of a drug, concealing known information on adverse reactions to the drug and information on adverse reactions to the drug reported by healthcare professionals.

As discussed in detail in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications** and **3.3 Provision of Information to Healthcare Professionals**, in practice, pharmaceutical companies in China are cautious about providing information on unauthorised medicines or unauthorised indications to avoid what might be constituted as illegal advertising. It is benchmark practice that the RDPAC Code requires such discussions to be conducted by or under the supervision of medical experts rather than personnel with commercial functions.

6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

6.1 Requirements for Prior Notification/ Authorisation

Under the Advertising Law, the Drug Administration Law and the Administrative Measures for Review of Drug Advertisements, drug advertisements are subject to review and approval by the drug regulatory department of the provincial-level government where the company is located (ie, the local NMPA), which must issue an approval number for the drug advertisement. An approval number is required before any drug advertisement can be made. The validity period of the approval must be consistent with the shortest validity period of the medicinal product registration certification or the manufacturing permit, and if no valid period is prescribed in such documents, the valid period for the approval will be two years.

After the approval is granted, the local NMPA will file the approved advertising with the NMPA for record. It is worth mentioning that the Administrative Measures for Review of Drug Advertisements have simplified the review and approval process. For example, apart from the traditional on-site application, application can also be submitted via letter, fax, email, or an e-government platform. Fewer documents are needed for approval. However, the content review will still strictly follow the applicable rules. The Measures also grant that approved advertisements may be published nationwide in accordance with the law.

6.2 Compliance with Rules on Medicinal Advertising

There is no legal requirement to adopt standard operating procedures (SOPs) or employ specific personnel. However, according to the RDPAC Code, a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. Alternatively, a senior company employee could be made responsible provided that they receive scientific advice on such communications from adequately qualified scientific personnel. In practice, large and medium-size pharmaceutical companies normally have their own SOPs guiding companies' advertising practices in order to guarantee legal compliance. Legal and/or compliance teams or external counsel may be involved to conduct compliance reviews of certain advertisements.

If the company entrusts an advertising agency to provide advertisement design or production or agent services on a commission basis, the Advertising Law requires advertising agencies and advertisement publishers to inspect and verify the relevant certification documents and check the advertising contents in accordance with the law and administrative regulations.

7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

7.1 Regulation of Advertising of Medicinal Products on the Internet

Under the Interim Measures for the Administration of Internet Advertising, internet advertising may take various formats such as text, images, audio, video, or other forms on websites, web pages, or in applications (such as WeChat). In addition to all the restrictions regarding advertising in general, a few additional requirements apply to internet advertising. For example, internet advertising cannot interfere with people's normal use of the network. Online pop-ups should be clearly marked with a closing sign to ensure a one-click closure. Advertisers may not deceive users into clicking on the advertising content. No advertisement or advertisement link may be attached to the emails sent by advertisers or their agents without the recipient's prior permission. It is also prohibited to publish advertisements for prescription drugs on the internet. Pharmaceutical advertising on the internet also requires approval by the local NMPA, subject to the restrictions applicable to drug advertisements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**).

In addition, the entity providing information on pharmaceuticals to online users via the internet is subject to the Qualification for Internet Drug Information Services issued by the competent local NMPA according to the Administrative Measures for Online Drug Information Services.

7.2 Advertising of Medicines on Social Media

The Interim Measures for the Administration of Internet Advertising cover advertising on social media as part of "internet advertising". Therefore, advertising on social media is generally allowed to the extent that internet advertising is allowed.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

The law in China does not explicitly require companies to include access restrictions on websites containing advertising or other information intended for healthcare professionals. In practice, many companies do have this arrangement in place, such as asking whether the user is a healthcare professional or conducting an identification verification before the user can access the contents on specific web pages or columns publishing scientific information on diseases and prescription drugs, to avoid being perceived as advertising prescription drugs to the public on the internet.

7.4 Provision of Disease Awareness Information to Patients Online

Provision of disease awareness information and/or materials to patients online is not legally prohibited but might be regarded by law enforcement as advertising if the information provided can be viewed as being promotional in nature or pointing to a specific product, as discussed in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

According to a summary of the relevant laws, provision of disease awareness information and/or materials to patients online, or in other ways to the general public, must be compliant with the following requirements:

- firstly, the provision should not include information on drugs, otherwise such provision will constitute advertising subject to approval for pharmaceutical advertising;
- secondly, the provision should not constitute retailing of pharmaceutical products without a distribution licence; and
- thirdly, other general rules on patient education also apply, including diagnosis and treatment not being included, not discrediting competitors, not constituting false promotion, etc.

7.5 Online Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor online scientific meetings or attendance by healthcare professionals of these online events. As with sponsoring of off-line scientific meetings, bribery in any form, such as provision of a participation subsidy, is strictly prohibited (see **9.3 Sponsorship of Scientific Meetings**).

PRC law is silent on the criteria required for an online meeting to be viewed as an "international" event. In practice, this generally depends on where the speakers and attendees come from. With reference to the RDPAC Code, it defines an "international" event as a scientific meeting where a significant proportion of the speakers and attendees come from countries other than the country in which the meeting takes place.

PRC law does not explicitly require prior authorisation in relation to healthcare professionals' participation in online scientific meetings, while in practice, pharmaceutical companies normally require doctors to obtain prior consent from their working hospital to ensure healthcare professionals are permitted to participate.

Separately, there are no special statutory requirements on (i) sharing handouts, materials, etc, during an online conference; or (ii) accessing conference recordings, materials, etc, after the date of the conference. For handouts and materials of an advertising nature, see **5. Advertising to Healthcare Professionals**. Also see **3.2 Provision of Information during a Scientific Conference**, which discusses providing information on unauthorised medicines or unauthorised indications.

8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery legal system includes laws on both the administrative and criminal levels.

Administrative Law

On the administrative level, the legal framework regulating commercial bribery is set out by the Drug Administrative Law, the Anti-Unfair Competition Law, together with the Interim Provisions on Banning Commercial Bribery, and a number of replies by the former SAIC on the handling of commercial bribery acts. The Drug Administrative Law states that:

- pharmaceutical companies and healthcare organisations may not offer or accept any kick-backs or improper benefits;
- pharmaceutical companies may not offer any improper benefits to healthcare professionals

or other related staff in any healthcare organisation which uses their drugs; and
- healthcare professionals and related staff of a healthcare organisation may not receive any improper benefits from the pharmaceutical companies.

The key provision under the Anti-Unfair Competition Law states that business operators may not resort to bribery, by offering money or goods or by any other means, to any of the following entities or individuals, in order to seek a transaction opportunity or competitive advantage:

- any employee of the counterparty to a transaction;
- any entity or individual entrusted by the counterparty to a transaction to handle relevant affairs; and
- any entity or individual that is likely to take advantage of powers or influence to affect a transaction.

Penalties for violation include fines ranging from RMB100,000 to RMB3 million, confiscation of illegal gains and revocation of business licences in serious cases. The legal representative, main person-in-charge and directly responsible staff may be prohibited from engaging in drug production and distribution activities for life.

Public Healthcare Institutions

In practice, with respect to public-funded healthcare institutions, law enforcement takes the view that the purchasing of medicines "pierces" through the healthcare institution and should actually be viewed as transactions that take place between the pharmaceutical industry and the patients/medical insurance fund. Under this theory, the patients/medical insurance fund become the counterparty to the transaction, and both healthcare institutions and healthcare professionals, with their power to prescribe medicines to patients, fall into the scope of entities and individuals having the power or influence to affect a transaction. As a result, the general anti-bribery rules apply to benefits provided to healthcare professionals and benefits provided to public healthcare institutions.

Adverse Records

Other than an administrative penalty, a pharmaceutical entity that conducts commercial bribery may also be discredited with an adverse record of commercial bribery by the provincial health commission. In this case, public medical institutions or medical and health institutions that receive financial funds from local government in that provincial region may not purchase medicines, medical equipment or medical supplies from such pharmaceutical entity within two years after the publication of the adverse records. If a pharmaceutical entity has adverse records of commercial bribery twice or more times within five years, all public medical institutions or medical and health institutions that receive financial funds across the country may not purchase medicines, medical equipment or medical supplies from such pharmaceutical entity. In addition, under the Drug Pricing and Procurement Creditworthiness System issued by the National Healthcare Security Administration, if the pharmaceutical entity takes part in commercial bribery, it will have an adverse credit and may be subject to negative treatment such as a warning, automatic risk heads-up in centralised procurement, and even suspension of listing or procurement, tendering and delivery of drugs.

Criminal Law

On a criminal level, Criminal Law prohibits both individuals and entities from bribing several types of recipients. These include:

- state functionaries;
- the close relatives of or other persons closely related to a state functionary;

- a former state functionary or close relatives of or other persons closely related to the former state functionary;
- state agencies, state-owned enterprises, public institutions or people's organisations;
- employees of a company; and
- foreign individuals performing official duties or officials of an international public organisation.

Penalties for individuals include fines or confiscation of property and criminal detention or fixed-term imprisonment ranging from three years to life imprisonment. For entities, penalties include fines and criminal detention or fixed-term imprisonment for up to five years for the responsible individuals.

8.2 Legislative or Self-Regulatory Provisions

The Drug Administration Law prohibits drug marketing licence holders, drug manufacturers, distributors and their agents from providing any property or other improper benefits to the responsible person, the procurement personnel, physicians, pharmacists and other relevant individuals of a health institution that uses their drugs. The listed categories of individuals are also prohibited from receiving these benefits.

Under the RDPAC Code, if a member company engages healthcare professionals to serve as the company's consultants or advisers, one of the requirements for such an engagement is that the hiring of the consultants or advisers to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine.

In regulatory practice, benefits provided to healthcare organisations for inducement to prescribe may be deemed as improper benefits and are therefore also forbidden. See **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** for a detailed discussion.

9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

9.1 Gifts to Healthcare Professionals

The Interim Provisions on Banning Commercial Bribery promulgated by the SAIC permit gifts of "small value" to be provided in the course of customary business practice and would not consider these to be commercial bribery. However, there is no legal guidance for the maximum amount of "small value".

Gifts (such as sporting or entertainment tickets, social courtesy gifts, etc) for the personal benefit of healthcare professionals, either directly or through clinics and institutions, are prohibited under the RDPAC Code. Providing or offering cash, cash equivalents, or personal services is also prohibited. For these purposes, "personal services" are any type of service unrelated to the healthcare professional's profession which confer a personal benefit to the healthcare professional.

However, promotional aids of minimal value (not more than RMB100 in value per item) and minimal quantity may be provided or offered to healthcare professionals solely for the promotion of over-the-counter medicines (but not prescription-only medicines) if relevant to the practice of the healthcare professional. Similarly, items of medical utility to enhance the provision of medical services and patient care are also conditionally permitted under the RDPAC Code with a limit of RMB500 per item. Even if each individual item is appropriate, such offering should not be made on more than an occasional basis.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to the RDPAC Code, samples of a limited quantity of a pharmaceutical product may be supplied directly to healthcare institutions so healthcare professionals can familiarise themselves with the product, but these should be delivered through a qualified third party. Samples should be marked as such so that they cannot be resold or otherwise misused. Member companies should have adequate systems of control and accountability for samples provided to healthcare professionals through healthcare institutions, with respect to the distribution, delivery and acceptance of samples.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor scientific meetings. Under the Administrative Measures for Review of Drug Advertisements, the sponsored event cannot be titled the same as the name of any prescription-only medicine and cannot be titled the same as a trade mark or trade name that is identical to the name of a prescription-only medicine.

Pharmaceutical companies are generally allowed to sponsor attendance of these events by healthcare professionals, but should be careful not to violate the rules against commercial bribery. Under the RDPAC Code, member companies may sponsor healthcare professionals to attend medical interaction programmes if such sponsorship complies with the following requirements:

- the programme itself complies with the requirements in the RDPAC Code;
- the sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- no payments are made to compensate healthcare professionals for time spent attending the programme;
- under no circumstances should a company make any payment or transfer any sponsorship funds directly to a healthcare professional or a hospital department; and
- any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Under the Interim Provisions on Banning Commercial Bribery promulgated by the SAIC, commercial bribery includes both monetary bribery and other means, where “other means” refers to non-monetary benefits, such as tours and field trips in China or abroad.

Similarly, under the RDPAC Code, no entertainment or other leisure or social activities may be provided or paid for by member companies. Cultural, sports, or other non-scientific events in relation to scientific conferences may easily fall into the scope of “entertainment or other leisure or social activities” and, therefore, are generally prohibited by the RDPAC Code.

Moreover, under the Nine Criteria issued by the National Health Commission, the National Healthcare Security Administration and National Administration of Traditional Chinese Medicine, healthcare professionals are prohibited from participating in entertainment activities arranged, organised, or paid for by pharmaceutical manufacturers, distributors, or their agents.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide grants or donations to healthcare institutions in accordance with the Administrative Measures for the Receipt of Public Welfare Donations. However, pharmaceutical companies are not allowed to

specifically appoint the healthcare professionals from the healthcare institutions as the recipients of donations.

Under the Measures, the requirements are generally similar for monetary donations and donations of equipment or services from a pharmaceutical companies' perspective. The differences between monetary donations and donations of equipment or services mainly concern the recipient institutions. For example, the recipient institutions are encouraged to use a third-party agency to confirm the value of non-monetary donations, and the ways in which recipient institutions can spend the donations differ depending on the type of donations.

Additionally, in practice, donations of equipment or services may be higher risk than monetary donations, because in addition to potentially violating the Measures, a wrongful donation of equipment or services may also be seen as offering equipment or services in connection with the sale of medicines under the prohibited buy-one-give-one model, thus violating the Provisions for Supervision of Drug Distribution.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

As discussed in **3.4 Provision of Information to Healthcare Institutions**, procurement of drugs in China is organised by the government through bidding on bidding platforms. As healthcare professionals and healthcare institutions are not directly involved in procurement, rebates or discounts provided to them are less common than in some other jurisdictions. Still, the Drug Administration Law explicitly prohibits drug marketing licence holders, pharmaceutical manufacturers, distributors and healthcare institutions from giving or receiving rebates or other improper benefits in the purchase and sale of drugs.

Moreover, under the Nine Criteria, healthcare professionals are prohibited from accepting any rebate offered by pharmaceutical manufacturers, distributors, or their agents in any name or form.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay for services provided by healthcare professionals under certain circumstances. For example, companies may invite healthcare professionals who are key opinion leaders in their fields to give lectures or to serve on the company's advisory boards and attend board meetings. Under these circumstances, companies may pay these healthcare professionals speaker fees or consultation fees at fair market value, as applicable.

The RDPAC Code sets out a large number of restrictions on the amount of payment allowed. Chief among these restrictions are: the hiring of the healthcare professional to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine, and the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Companies' SOPs may set out more specific restrictions on the amount of speaker fees, consultation fees and relevant expenses for meals and transportation, and may require employees to provide documents to prove the services provided by the healthcare professionals. For example, the SOP may establish the maximum amounts allowed for domestic and international lectures and meetings. The SOP may also state that, for foreign speakers or consultants, the payment must comply with the fair market value of their respective countries of origin.

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The law in China does not explicitly require prior authorisations or notifications in relation to gifts, hospitality, congresses and related payments described in this section. In practice, however, employers often do require that employees obtain prior consent from their employer before engaging in such activities.

In particular, doctors employed by medical institutions cannot practise outside the registered medical institution without due record-filing, and their personal activities are more closely managed by the registered medical institutions. Their activities in relation to gifts, hospitality, congresses and related payments described in this section will likely require the employer's prior consent.

10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The law in China does not provide explicit disclosure requirements for pharmaceutical companies and there is no specific statutory requirement being applied to such disclosure obligation due to COVID-19.

Having said that, industry benchmark standards can be found in self-regulatory codes. For example, the RDPAC Code states that if material relating to pharmaceutical products and their uses, whether promotional in nature or not, is sponsored by a member company at medical interaction programmes between member companies and healthcare professionals, that material should clearly indicate by whom it has been sponsored. Medical interaction programmes hosted or sponsored by member companies, whether promotional in nature or not, should clearly indicate by whom they have been hosted or sponsored. If a member company sponsors medical interaction programmes organised by a third party, the above disclosure should be made subject to the knowledge and consent of the organiser.

Healthcare institutions that receive donations are subject to disclosure requirements. Under the Administrative Measures for the Receipt of Public Welfare Donations, the recipient institution must establish a publication system for donation information and must publish donation receipt information to the society in an authentic, accurate, timely and complete manner via their web portals or local major news media.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

There are no explicit legal transparency requirements for foreign companies, although certain self-regulatory codes, such as the RDPAC Code, impose disclosure requirements on their member companies. As self-regulatory codes are contractual in nature, whether a company is subject to these requirements depends on whether the company undertakes to enter into the contractual arrangement as one of its members. If a company undertakes to be bound by certain self-regulatory codes, it will be subject to the same transparency requirements regardless of whether the company is domestic or foreign and regardless of whether its products are already on the market.

11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

11.1 Pharmaceutical Advertising: Enforcement Bodies

The SAMR

Until 2018, the SAIC and its local branches were responsible for enforcing the rules on advertising and the rules on inducement. Since the government restructuring in 2018, the SAIC has become part of the State Administration for Market Regulation (SAMR) which, together with its local branches, is responsible for enforcement actions. The restructuring enabled the SAMR to combine the SAIC's enforcement mechanism and the NMPA's familiarity with the pharmaceutical industry, as a result of which, supervision of this industry has been strengthened.

The RDPAC Code

The RDPAC Code has also created its own dispute resolution system, providing member companies with the opportunity to file complaints against competitors and to request that the association enforce its rules through the established panel review, mediation, or sanction procedures.

The People's Court

In the event that a pharmaceutical advertisement is recognised as false advertising, causing damage to the legitimate rights and interests of consumers, the consumers may file a lawsuit with the people's court and claim for damages.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Companies can initiate proceedings against competitors in court for advertising infringements on the basis of the Anti-Unfair Competition Law and the Civil Procedure Law. Companies may also file complaints against competitors with the State Administration for Market Regulation or its local branches in accordance with the provisions in the Law on Administrative Penalty. Additionally, member companies may also initiate panel review or meditation procedures as established by the RDPAC Code.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The penalties or measures that regulators or courts can impose for violating medicine advertising rules are mainly found in the Advertising Law and the Administrative Measures for Review of Drug Advertisements. The penalties and measures include ordering the cessation of the publishing of the advertisement, ordering the advertisers to eliminate negative impact, imposing fines, confiscating advertising fees and revoking business licences and approval documents for the advertisement. The penalties can be imposed on the advertiser, the advertising agency, or the advertising publisher (such as TV stations). The penalties imposed are listed in the National Enterprise Credit Information Publicity System for public notification as required by the Administrative Measures for Review of Drug Advertisements.

For example, in the case of false advertising, law enforcement will order that the advertisement be stopped and that the advertiser eliminate the negative impact. The advertiser may be fined the equivalent of three to five times the advertising costs; if the advertising costs cannot be calculated or are obviously low, the amount will be RMB200,000 to RMB1 million. Where violations happen three or more times within two years, or where the circumstances are serious, a fine of five to ten times the advertising cost will be imposed. If the advertising cost cannot be calculated or is obviously low, a fine of RMB1 million to RMB2 million will be imposed, the business licence may be revoked and the local NMPA may

revoke the advertisement's review and approval document and not accept applications from the advertiser for one year.

In serious cases, there may be criminal responsibilities too. For example, false advertising may result in criminal detention or fixed-term imprisonment of up to two years for advertisers, advertising agencies, or advertising publishers. Criminal fines may also be imposed separately or concurrently.

With regard to inducements to prescribe, if a case involves commercial bribery, then the penalties under the Anti-Unfair Competition Law and the Criminal Law discussed above will become relevant.

11.4 Relationship between Regulatory Authorities and Courts

There is no direct relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by the courts. The former is not a prerequisite for the latter. Specifically, regarding the RDPAC Code, there has yet to be any case where a court has considered a decision under the RDPAC Code as a basis for the court's decisions.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

From 2017 to now, an increasing number of cases have been investigated and penalised by the law enforcement authorities. This might be relevant to the 2018 government restructuring discussed in **11.1 Pharmaceutical Advertising: Enforcement Bodies**. It is anticipated that cases related to pharmaceutical advertising might increase after the Administrative Measures for Review of Drug Advertisements have been implemented for a longer time and before the advertisers become familiar with the new rules, because they impose new requirements on advertisers and clearer guidance to law enforcement officials.

In practice, the main reasons that penalties are imposed on illegal pharmaceutical advertising include:

- the pharmaceutical advertising is published without approval;
- the pharmaceutical advertising of prescription-only drugs is publicly published on media other than the pharmaceutical or medical journals designated by the Ministry of Health and the NMPA;
- the pharmaceutical advertising does not list contraindications or adverse reactions and goes beyond the scope of its instructions; and
- the drugs advertised are not permitted to be advertised, eg, narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs.

In a renowned law enforcement case in recent years, an over-the-counter pharmaceutical company published its pharmaceutical advertising three times on a popular domestic variety show and was fined RMB900,000 for the reasons specified in bullet points one and three above. In March 2021, a branch of the SAMR in Shanghai imposed a fine of RMB200,000 on a pharmaceutical entity for the reasons specified in bullet points one and two above, because the pharmaceutical entity had published an article via online media recommending a prescription-only drug.

Global Law Office was one of the first law firms in the PRC, dating back to 1979, and is one of the largest, with around 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. The life sciences and healthcare (L&H) practice group is one of the leading advisers in China, providing "one-stop" legal services for every area of the L&H industry, including drug R&D, clinical research organisations, pharmaceuticals, life sciences, biotechnology, medical devices, supply producers and distributors, hospitals and other healthcare providers, as well as various investment funds in the L&H sector. Global Law Office advises clients on challenging L&H legal issues, such as regulatory compliance, structuring transactions and contractual arrangements, realisation of pipeline and geographic expansions, capital raising and project financing, M&A, reorganisations, IP protection, licensing and distribution arrangements, settlement of disputes involving adverse effects in clinical trials and medical treatment. The firm has close links to industrial associations and makes recommendations on industry codes of conduct and compliance management standards.

AUTHORS

Alan Zhou is the leading partner in the life sciences and healthcare (L&H) team at Global Law Office, with a strong background in L&H practice. He focuses on M&A, private equity/venture capital, regulatory compliance and general corporate. Alan has routinely represented multinational corporations, such as Sanofi, Siemens, AstraZeneca, GSK, Boehringer Ingelheim and Novartis, as well as local L&H companies. As a participant or external counsel, he has been engaged by local authorities and industrial associations to advise on legislation and industrial standards in the L&H industry, on topics including online hospitals, digital marketing, medial insurance reform, medical representative management and other compliance topics.

Xuchun Huang (Charlene) is a partner at Global Law Office. She specialises in cross-border acquisitions and foreign investment and has in-depth experience advising multinational companies in general corporate, cybersecurity and data management. Her clients are in the healthcare industries and her transactions include greenfield foreign investment in the form of joint ventures or wholly foreign-owned enterprises, acquisitions of equity interests in Chinese state-owned or private companies, the restructure or integration of China-based businesses of multinational companies, strategic co-operation, etc. Charlene has given day-to-day advice and worked on substantial projects for Abbott, Align Tech, Boehringer Ingelheim, Eli Lilly, GE, the HRC, etc.

Xuan He (Samantha) is an of counsel at Global Law Office. Her practice is primarily focused on the life sciences industry, and she has represented a number of major life sciences companies on compliance and regulatory matters and corporate issues. Through significant experience in the life sciences industry, she has acquired insights into the evolving legal and regulatory landscape in China. She advises clients on regulatory matters across a range of sectors, including drugs and biologics, medical devices, and e-health products and services. Samantha also counsels clients on regulatory and compliance issues, including advertising, anti-corruption and bribery, medical affairs, manufacturing and distribution.

Qiuyan Dong (Sylvia) is an of counsel at Global Law Office. Her main practice covers M&A, private equity/venture capital and the capital market, and she is especially focused on the life sciences industry. She has represented well-known clients in various domestic and cross-border transactions, strategic investments and collaborations, as well as securities offerings and bond offerings. She has rich experience in investment, licence deals, business collaborations, general corporate and compliance in the life sciences and healthcare industries.

Global Law Office

36th Floor
Shanghai One ICC
No 999 Middle Huai Hai Road
Xuhui District
Shanghai 200031
China

Tel: +86 021 2310 8288
Fax: +86 021 2310 8299
Email: alanzhou@glo.com.cn
Web: www.glo.com.cn

环球律师事务所
GLOBAL LAW OFFICE