PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The Advertising Law is the pivotal law governing advertising activities in China. There are various implementing rules governing specific activities (eg, the Provisional Administrative Measures on Internet Advertisement) and specific products or services (eg, the Administrative Measures on Healthcare Advertisement). The Drug Administrative Law and the Medical Devices Administrative Regulations set out the general requirements on the advertising of pharmaceuticals and medical devices respectively. Local government authorities at provincial and municipal levels also promulgate local laws, regulations, protocols and guidelines under the Advertising Law. Additionally, industry associations and self-regulatory bodies often have their own codes of practice that members are expected to follow.

For the sole purpose of answering the survey questions, Chinese law or the Law of the People's Republic of China (the 'PRC law') shall be interpreted narrowly to cover only the laws applicable in mainland China.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Under PRC law, the Advertising Law governs 'commercial advertising activities', defined as the direct or indirect promotion of commodities or services through certain media and format. The traditional forms of advertisement are TV commercials and outdoor advertisements. In recent years, regulators also introduced new laws and regulations to regulate advertising in novel formats, such as precision advertising, live streaming advertising, and advertisements embedded in movies and TV dramas.

There is no clear-cut differentiation between promotion and advertising in China. Promotion usually refers to general marketing activities such as product information dissemination, academic promotion, and brand promotion while advertising usually refers to commercial advertising targeting the general public. Advertising is regarded as part of the promotion and is regulated by the Advertising Law.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The State Administration for Market Regulation and its local subordinates (SAMR) is generally responsible for the supervision of all advertising activities in China. In relation to the advertising of pharmaceuticals and medical devices, SAMR works with the National Medical Products Administration (NMPA) in the enforcement of law.

Self-regulatory processes, often led by industry associations, complement the work of these authorities by setting industry standards and promoting best practices. Pharmaceutical companies and medical devices companies also typically have legal and compliance teams, supported by outside counsels, to ensure compliance with law.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Advertising activities of heath foods and Foods for Special Medical Purposes (FSMP) are similarly regulated, although the regulatory requirements differ in detail depending on the product category and the intended use. For example, advertisements on pharmaceuticals, medical devices, health foods and FSMP are all subject to prior approval by the regulatory authorities and no individuals or entities may endorse these products.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

The promotion and advertising of pharmaceuticals or medical devices are subject to various regulatory restrictions under PRC law, including without limitation the following:

- the following products may not be advertised: special pharmaceuticals such as anesthetics, psychotropic drugs, toxic drugs for medical use, and radioactive drugs; drug-like precursor chemicals; and drugs, medical devices, and treatment methods for drug addiction treatment;
- advertisements for pharmaceuticals and medical devices shall not be published in mass media targeting minors;
- prescription drugs shall only be advertised in scientific journals;
- the advertisements of pharmaceuticals and medical devices shall be subject to prior approval by the regulatory authorities;
- the advertisements of pharmaceuticals and medical devices shall not guarantee the safety or efficacy of the products; and
- the advertisements of pharmaceuticals shall be consistent with the label and shall clearly state contraindications and adverse reactions of the product.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Yes, the promotion and advertising of pharmaceuticals and medical devices through the internet and social media is heavily regulated in China. The relevant laws and regulations stipulate that such activities must comply with the same standards and restrictions as traditional media. Additionally, specific rules may apply to online advertising, such as requirements for clear and conspicuous disclosures, prohibitions on misleading or deceptive content, and restrictions on the use of endorsements or testimonials.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

In China, commercial advertisements for pharmaceuticals and medical devices typically require prior approval from the relevant regulatory authorities before they can be used. The specific procedure may vary depending on the type of product and the intended audience but generally involves submitting an application along with the advertising materials to the appropriate authority for review and approval. The authority will assess the materials against the relevant laws and regulations to ensure compliance and may request modifications or reject the application if necessary.

If a promotion activity (eg, one-on-one promotion) does not fall under the definition of commercial advertising, such approval may not be required. However, the authority has great discretion to determine if the nature of the promotion activity constitutes commercial advertising.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

In China, it is generally not permissible to promote or advertise unauthorised pharmaceuticals or off-label information. Such activities are considered illegal and may result in severe penalties. However, there may be exceptions under specific circumstances, such as providing scientific or educational information to healthcare professionals or conducting clinical trials. These exceptions are strictly regulated and require prior approval from the relevant authorities.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Comparative advertisements for pharmaceuticals and medical devices in China are subject to strict regulation. The relevant regulations stipulate that such advertisements must comply with fairness, truthfulness, and objectivity principles and must not mislead consumers or damage the reputation of other products. It is generally not allowed to use another company's information (including brand name) as part of the comparison without their consent. Additionally, it is generally not permitted to refer to a competitor's product or indication that has not yet been authorised in China.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Under PRC law, 'healthcare professionals' are defined as professional medical personnel who have obtained the qualification of medical practitioners according to law and are registered to practise in medical and health institutions, including practising physicians and practising assistant physicians.

There are regulations that restrict promotional and advertising communications directed to healthcare professionals, mainly to ensure that such communications do not interfere with medical practice or mislead healthcare professionals. These restrictions include prohibitions on directly or indirectly providing gifts, kick-backs or other benefits, engaging in false, misleading or exaggerated claims, and promoting unauthorised product or off-label use.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

Yes, there are specific rules governing promotional and advertising activities conducted virtually, including online interactions with healthcare professionals, virtual meetings, and participation in virtual congresses and symposia. These rules aim to ensure that such activities comply with the relevant laws, regulations and ethical standards, including obtaining necessary approvals, ensuring the correct scope of audience, ensuring the accuracy and truthfulness of information, restricting the promotion of pipeline products, and avoiding conflicts of interest.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

In relation to the advertising of healthcare services, pharmaceuticals and medical devices, the inclusion of endorsements by healthcare professionals in promotional and advertising materials is not permitted under PRC law.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Pharmaceutical companies and medical device companies can provide healthcare professionals with reasonable samples of medicinal products or medical devices in China through the medical institutions the healthcare professionals are affiliated with, subject to specific circumstances and strict regulation.

Except for limited exceptions, gifts to healthcare professionals are prohibited. In some circumstances, offering promotional aids with minimal value and quantity for the purpose of the promotion may be permitted, subject to specific regulations and institutional policies.

Donations of money to healthcare professionals are not permitted generally. Donations to medical institutions are possible but subject to strict regulations.

14. What rules govern the offering of hospitality to healthcare professionals?

The offering of hospitality to healthcare professionals in China is subject to strict regulation. Such hospitality must comply with the relevant laws, regulations, and ethical standards, including ensuring its truthfulness, necessity, reasonableness, and transparency. Additionally, there are specific limits on the purpose, value and type of hospitality that can be offered. We are happy to advise more on the legal and customary standard in China regarding such limits upon request.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

As discussed above, donations to medical institutions are permissible but subject to strict regulations. One of the key conditions is that the donation must be for public interest and shall not relate to any business conditions or purposes.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Yes, pharmaceutical laboratories or medical device manufacturers or their licensees may support scientific or educational meetings in China, as long as they comply with legal requirements.

There are minor differences in the rules governing these two sectors from the perspective of product promotion. For example, the promotion of prescription drugs may be subject to stricter regulation than Class I devices due to the difference in their impact on human health.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

In China, the key rules governing the relationships between pharmaceutical/medical devices companies and patient organisations are transparency, legitimacy, and compliance with anti-corruption and advertising regulations. Funding must be lawful, transparent, and not influence the independence or decision-making of patient organisations. Both parties are responsible for disclosing potential conflicts of interest.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

A company can delegate promotional and advertising activities to advertising companies or integrated marketing companies in China under a fee-for-service arrangement. Co-promotion is permitted and is generally subject to the Advertising Law.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

In China, while not expressly required by law, many permit/authorisation holders and medical institutions have ethical guidelines or rules which require the reporting of transfers of value made to healthcare professionals, subject to specific thresholds and reporting requirements. Such reporting aims to enhance transparency and accountability in the healthcare sector and prevent potential corruption or conflicts of interest.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Violations related to the promotion and advertising of pharmaceuticals and medical devices in China are subject to various penalties and sanctions, including warnings, fines, confiscation of illegal gains, revocation of permits or authorisations, and criminal liability in severe cases. The authorities actively impose these penalties and sanctions to ensure compliance with the relevant laws and regulations. Penalties and sanctions are typically announced publicly to enhance transparency and deter future violations.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

As discussed above, SAMR and NMPA authorities are primarily responsible for enforcement. Enforcement of the Advertising Law is rigorous, especially in the pharmaceutical and medical devices sectors. Few competitors take action through the courts in relation to promotion (advertising) infringements, but it is not uncommon that competitors report infringements to the authorities as whistleblowers.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

In recent years, Chinese regulators have introduced new laws, regulations and guidelines to regulate advertising through new media and novel formats, including without limitation precision advertising, live-

streaming advertising, virtual congresses and symposia, and advertisements embedded in movies and TV dramas. Enforcement activities in these areas are likely to increase in the future.