

**Baker
McKenzie.**

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



CHINA

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China

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Introduction

Advertising and promotion of pharmaceuticals and medical devices are subject to strict regulations in China. Approval requirements for advertisements and strict product labeling requirements are issues that multinational pharmaceutical and medical device manufacturers often contend. On top of that, laws of anti-unfair competition and anti-bribery, together with the US Foreign Corrupt Practices Act, make marketing and promotion of pharmaceutical and medical device products particularly difficult in China.

The pharmaceutical and medical device distribution sector has been undergoing changes and consolidation. Authorities have been targeting bribery activities in the sector and there has been strong emphasis by foreign companies to implement strict compliance policies in all business activities including advertising and promotion. Apart from internal policy, the professional industry body has also promulgated ethical industry codes of conduct on business activities.

The Regulatory Framework

In China, there is no one comprehensive law or regulation that governs the conduct of advertising and promotion of pharmaceutical products and medical devices. The relevant legislation that govern advertisement and promotional activities concerning medical products and services are found in both national and local level laws, administrative regulations and orders.

The main laws and regulations include the following:

Laws governing general advertising

- Advertising Law of the People's Republic of China (1995)

- Detailed Implementing Rules of Advertising Law of the PRC (2005)

Laws governing pharmaceuticals generally

- Law for the Administration of Pharmaceuticals (2001)
- Implementing Regulations for the Pharmaceuticals Law (2002)

Laws relating to advertising of pharmaceuticals

- Measures for the Examination of Pharmaceutical Advertisements (2007)
- Standards for the Examination and Publication of Pharmaceutical Advertisements (2007)

Laws governing medical devices generally

- Regulations on Supervision and Administration of Medical Device (2000)
- Measures for the Administration of Medical Device Registration (2004)

Laws relating to advertising of medical devices

- Measures for Examination of Advertisement for Medical Device (2009)
- Standards for Examination and Release of Medical Device Advertisements (2009)
- Measures for the Administration of User Manuals for, Labels of, and Markings of Packages of Medical Devices (2004)
- Warning System for Illegal Advertisements for Pharmaceuticals, Medical Devices and Health Foods (Trial regulations, issued 2006)



Under the Advertising Law, the term “advertising” or “advertisement” is defined as “commercial advertising or commercial advertisement by which a dealer in merchandise or a provider of services directly or indirectly introduces, at his own expense, through a certain medium and in a certain form, merchandise marketed or services provided by him.”

Consistent with the general broad definition of “advertisement,” “pharmaceutical advertisement,” as defined in the Measures for the Examination of Pharmaceutical Advertisements, also covers a potentially wide range of activities, particularly, “any advertisement published through various media or forms which contain the name of a pharmaceutical product, indications (functions) or other relevant contents of a pharmaceutical product.”

Likewise, in the Measures for the Examination of Medical Device Advertisements, “medical device advertisement” is defined as “any advertisement published through a certain medium and in a certain form which contain a medical device’s name, scope of use, components and physical make-up, or mechanism of a medical device product.”

The broad definition of “advertising/advertisement” implies that the scope is wide and it should be assumed that any or all advertising or promotional activities of pharmaceutical products and medical devices regardless of the form and media in which it is released, published, or delivered, could be subject to the control and restrictions of the above mentioned regulations on medical advertising.

However, it should be noted that the above advertising regulations do not readily govern product promotional activities targeting medical institutions and practitioners. Instead, these advertising and promotional activities are regulated under local anti-unfair competition laws and anti-bribery laws and regulations.

The following are laws relating to unfair competition/anti-bribery:

- Anti-Unfair Competition Law of the People's Republic of China (1994)
- Several Provisions on Countering Unfair Competition in the Medical Industry (1993)
- Provisional Regulations on Prohibition of Commercial Bribery (1996)
- Provisional Measures for the Administration of the Acceptance by Medical and Health Institutions of Private Donations (2007)
- Measures on Establishing Bad Record for Commercial Bribery in the Purchase and Sale of Medical Products (2007)
- Opinions on Several Issues Concerning the Application of the Law in the Handling of Criminal Cases of Commercial Bribery (2008)
- Notice on Strengthening the Regulations on Commercial Bribery in the Purchase and Sale of Medical Products (2010)

General Requirements

The general regulatory framework on the advertisement of pharmaceuticals and medical devices can be summarized as follows:

Pharmaceuticals

- Publication, release or other forms of dissemination of pharmaceutical advertisements requires a "Pharmaceutical Advertisement Permit" from the relevant local food and drug administration authority.
- The advertisement permit is valid for one year.
- Publication or release of a drug advertisement in locations other than where the advertisement permit is issued requires a



pre-publication recordal with the local food and drug administration authority of the target advertisement location.

- Pre-approval is not required if the advertisement promotes only the name of an over-the-counter (“OTC”) drug, or if the advertisement only promotes the name of a prescription drug and is published in designated medical professional journals.
- Advertisement of certain drugs, including narcotics, psychotropic drugs, radiopharmaceuticals, specialty drugs used by the military and drugs only permitted for trial use, is strictly prohibited.
- Advertisement of prescription drugs is only permitted for medical professional journals, and is strictly prohibited for the general public.

Medical Devices

- Publication, release or any form of dissemination of advertisements on medical devices requires a “Medical Device Advertisement Permit” from the relevant local food and drug administration authority.
- The advertisement permit is valid for one year.
- Pre-release approval is not required if the advertisement contains only the name of the medical device and includes the medical device registration number.
- Advertisements of certain medical devices, including unregistered medical devices (where product registration is required), devices for trial use in clinical studies, devices under trial production, devices manufactured without requisite manufacturing license, or other devices that run afoul of social conventions or moral principles are strictly prohibited.

Permitted and Prohibited Practices - Advertisements

The following is a summary and an illustrative list of the main dos and don'ts for conducting advertising activities for medical products in China.

Pharmaceuticals

- Obtain pre-publication approval unless exemptions apply.
- Be truthful and not misleading.
- List product name, required legends, advertisement permit number, product manufacturing permit number and the drug manufacturer/distributor.
- Always use generic product name in advertisements (i.e., cannot use brand name only in advertisements); generic product names must be displayed more prominently than brand names.
- Do not use unscientific assertions or claims regarding efficacy or usage claims.
- Do not conduct comparative advertising with similar products, or conduct “before and after” references for own product.
- Do not use superlative language.
- Do not use references to cure rate, efficacy rate or product awards.
- Do not use the name or images of medical institutions, academic institutions, doctors, and patients as testimonials to the advertised claims.
- Do not publish advertisements on publications or press media that target minors or otherwise to appeal to minors, or advertise in the name of a minor.



- Do not advertise for narcotics, psychotropic drugs, poisons for medical use, radiopharmaceuticals or drugs specially needed by the army.
- Do not use unregistered trademark in drug advertisements; use registered trademarks together with generic product name.
- Only licensed drug manufacturers or distributors can apply for drug advertisement permits.

Specifically, for advertising of prescription drugs:

- Advertise only in medical and pharmaceutical industry publications - not in mass media or media of general distribution.
- Include the legend “for medical science and pharmaceutical professionals only.”
- If product name is the same as a trademark or a trade name, do not conduct “disguised advertising” by using the trademark/trade name in advertisements of general distribution.

For advertising of OTC drugs:

- Advertise in general media and in medical and professional publications.
- Include the legend “please purchase and use the product in accordance with instructions or under the guidance of a pharmacist.”
- Include the “OTC” marking in the packaging.
- Do not use misleading language, including technical medical terms that may be difficult for the general public to understand.

Medical Devices

- Obtain pre-publication approval unless exemptions apply.
- Be truthful, scientific, accurate and not misleading.
- List product name, advertisement permit number, product registration number and the manufacturer.
- Include the legend “please read the product excerpts carefully or purchase and use under the guidance of medical professionals” if the product is recommended for use by individuals.
- Do not use unscientific assertions or promises regarding efficacy or usage claims.
- Do not conduct comparative advertising with similar products, or conduct “before and after” references for own product.
- Do not use superlative language.
- Do not use language such as “must have for the family”.
- Do not use references to cure rate, efficacy rate or product awards.
- Do not use the name or images of medical institutions, academic institutions, doctors, and patients as testimonials to the advertised claims.
- Do not publish advertisements on publications or press media that are targeted at minors or otherwise to appeal to minors, or advertise in the name of a minor.
- Do not advertise using non-medical device product names in place of medical device product names.
- Only licensed medical device manufacturers or distributors can apply for medical device advertisement permits.



Permitted and Prohibited Practices – Other Promotional Activities

Under the Several Provisions on Countering Unfair Competition in the Medical Industry, companies may not entice buyers to purchase their products by providing money, goods, free trips, reimbursements of costs or other means that are considered as “bribery.” In general, “bribery” is defined by whether its purpose is to solicit business.

The Provisional Regulations on Prohibition of Commercial Bribery further recognizes that payments made in the guise of covering marketing or publicity expenses, sponsorship fees, R&D costs, service or consulting fees, sales commissions and the like may be deemed “commercial bribery” if they are made in order to induce purchases or sales of goods.

Gifts

Gifts to healthcare professionals and medical institutions may be permissible if such gifts are of “modest value” and given in accordance with customary business practices. Generally, the following two types of gifts are viewed as permissible in China:

- Gifts in kind (not cash) with the company name/logo printed or engraved on the gift item, such as a pen; under PRC law, this sort of gifts will be treated as a form of advertising by the company.
- Gifts made in connection with major events or festivals, such as birthday parties, funerals, the Spring Festival or the Mid-Autumn Festival.

In practice, one should generally keep the unit value of promotional gift items below RMB100, and gifts in connection with holidays below RMB200.

Sample Products

Sample products of “modest value” that are provided for promotional purposes should not be problematic.

Commercial bribery rules only prohibit the act of giving items of value for the purpose of soliciting purchases. “Hospitality” (e.g., meals and accommodation provided to healthcare professionals during business events) does not fall within this definition if it is incidental to business activities and is not intended to influence the purchasing decision. The hospitality should be directly related to the business event and the expense should not exceed reasonable amounts.

Lavish meals, meals outside the agenda of the business event, or reimbursing personal room charges such as room service or telephone calls, would likely be viewed as inappropriate.

Entertainment

The entertainment should be incidental to business activities and not intended to influence decisions. Furthermore, it should be directly related to the business event and the expense should not exceed reasonable amounts. Golf outings or performances by celebrities would likely be viewed as inappropriate.

Sponsorship for Training, Research, Employee Positions or Events

Sponsorship for training or events provided by medical device companies to employees of medical institutions may be prohibited as “commercial bribery,” if they are provided to influence the purchasing decision and they provide a benefit for the employee. Otherwise, they may be analyzed in the context of “donations” (see below) or “discounted items.”

Discounted Products

Under the Anti-Unfair Competition Law of the People’s Republic of China, discounts have to be “above board” and have to be properly recorded on the books of both parties. A secret, off-the-book rebate to a business unit or an individual will be treated as a “bribe.”

Donations

Charitable donations to hospitals are governed by the Provisional Measures for the Administration of the Acceptance by Medical and Health Institutions of Private Donations. These provisional measures



require, *inter alia*, that the donation not be made for any profit-making purpose, not be linked to any conditions, and be made for the benefit of the public.

If a donation does not satisfy the above criteria, it may be analyzed under the same structure as discounted products. The arrangement has to be “above board,” i.e., it has been properly documented and recorded in the books of both parties.

Consequences of Breach

The liabilities for violations of applicable advertising regulations vary depending on the type of conduct and violation. However, they mainly include the following types of penalty:

- Revocation of the related (drug or medical device) advertisement permits
- A ban (up to three years) for a new (advertising) permit
- Suspension of the advertisement in question
- Suspension of manufacturing, sale and use of the product
- Administrative fine (from RMB10,000 to RMB30,000)

Professional Codes of Conduct

The R&D Based Pharmaceutical Association of China (“RDPAC”), which is an industry body in the pharmaceutical industry, promulgated and issued the Code of Practice on the Promotion of Pharmaceutical Products (“RDPAC Code”) in 2003, which set forth standards for the ethical promotion of pharmaceutical products to healthcare professionals and for the interactions of the medical industry with them.

The latest version of the RDPAC Code was issued in 2010, with 37 pharmaceutical companies member signatories, all of which are major

multinational, research-based companies with substantial investment in China.

The general principles on the promotion of medical products and services set out by the RDPAC Code are as follows:

- Purpose of interaction - Interactions with healthcare professionals are intended to benefit patients and enhance the quality of medical services by providing the professionals with product information and scientific and educational information, among others.
- Independence of healthcare professionals - No financial benefit or benefit-in-kind may be offered to healthcare professionals in exchange for prescribing, recommending, purchasing, supplying or administering products, or to cause inappropriate influence on the prescribing practices of the professional.
- Appropriate use - Promotion should encourage the appropriate use of pharmaceutical products through objective introduction.
- Chinese laws and other local regulations - In all cases, all applicable Chinese laws and regulations must be observed and checked in advance of promotional actions.
- Transparency of promotion - Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must not be disguised promotion.
- Pre-approval communications - No pharmaceutical product shall be promoted for use in China until drug registration approval for marketing purposes has been granted.

Promotional Practices

In accordance with the RDPAC Code, promotional information should be:



- Consistent with product information approved by Chinese drug administration authorities;
- Clear, legible, accurate, balanced, fair, objective and sufficient enough to enable the recipient to form his or her own opinion of the therapeutic value of the products concerned; and
- Can be substantiated either by reference to approved product excerpts or by scientific evidence.

Seminars, Meetings, or Other Promotional Events

Seminars, meetings, or other promotional scientific or professional events for healthcare professionals sponsored or organized by the medical industry shall focus on providing information about the products and scientific developments, among others.

Events should be held in an appropriate venue that is conducive to the objectives and purpose of the event; extravagant venues should be avoided.

Events held outside of China are allowed only if a significant portion of the invited professionals are from overseas and it is feasible to hold the event in another country, or if the resource or expertise in relation with the subject matter of the event is located outside of China.

Companies are permitted to sponsor healthcare professionals' attendance to medical events. However, the support is strictly limited to the payment of travel, meals, accommodation and registration fees. Payment to professionals for the time spent in attending the event is strictly prohibited, except for reasonable fees and reimbursement paid to the speakers or presenters at the event.

Sponsored meal expenses should be incidental to the main purpose of the event, subject to moderate and reasonable local standards, and not be more than RMB300 per person per meal.

For events involving overnight stay, it should be ensured that the healthcare professionals spend a majority of the time on scientific or educational activities.

Entertainment will only be allowed only if it is secondary to the main purpose of the event and is provided during or directly before or after the meal or refreshment.

There should be no sponsorship of entertainment or other leisure or social activities unrelated to the events, such as sports contests, sightseeing, excursions, theatre or opera trips.

In all events, the recipient of all allowed sponsorship by the industry shall be healthcare professionals who attend the event and it should not extend to guests who accompany the professionals, such as relatives and friends.

Gifts

In principle, gifts for personal use, cash or cash equivalents should not be offered to healthcare professionals, except for the following items:

- Promotional aids or souvenirs of minimal value which are relevant to the practice of the healthcare professional (e.g., pens, notepads and surgical gloves)
- Items of medical utility of modest value that are beneficial to the provision of medical services and for patient care (e.g., medical books and anatomical models)
- Gifts with value of no more than RMB200 given on an infrequent basis in acknowledgment of official holidays in China

Samples

Free samples of a medical product of a limited quantity may only be supplied to healthcare professionals for the purpose of familiarization with the product and further enhancement of patient care. Samples



should be clearly identified as “Sample” or “Not for Sale” and should not be resold or otherwise misused.

Criminal and Civil Liabilities

Liabilities for Violation of Anti-Bribery Laws

The liabilities applicable to violations of anti-commercial bribery laws include the following:

- Administrative fine in the range of RMB10,000 to RMB200,000
- Confiscation of illegal gains
- Criminal liabilities (for parties that commit bribery acts)

Public Procurement and Fraud

Public medical institutions in China are mostly government-owned. Procurement of drugs and medical device products is done under a centralized system of public procurement and tendering.

Medical products purchased by public medical institutions (including non-profit medical institutions that are state-owned) are subject to public procurement and tendering rules.

In the process of bidding for government tenders, the following acts will likely be deemed as violation:

- Committing acts of false advertising, commercial bribery or other anti-fair competition acts
- Providing bids in bad faith (e.g., bids with prices lower than costs)
- Colluding with other bidders on bidding prices to disrupt the order of the procurement process

- Offering bribes to procuring entities, medical institutions or individuals for illegal gains
- Providing fraudulent documentation or commit fraud by other means
- Refusing to enter into sales and procurement contracts within a prescribed timeline or failing to perform obligations under the agreements
- Raising the price of selected products without approval or raising the price in a disguised form
- Refusing to deliver or failing to deliver on time selected products and in so doing causing product shortage at the medical institution

Any violation will be published on the website of the local health authority, and companies with such adverse records will be barred from bidding for other government tenders for two years.

Contracts with Healthcare Professionals and Medical Institutions

There are no express laws or regulations that govern contracts with healthcare professionals and medical institutions.

However, the RDPAC Code provides that, for arrangements for health professionals to give speech or presentations at events or to provide other consultancy services, medical companies should enter into written agreements with the said professionals, and that the agreements should set out clear provisions regarding compensation and other reasonable reimbursements.

Recommendations

The following are rules of thumb when conducting advertising and promotional activities concerning medical products in China:



- Follow the rules on general advertising of medical products – observe the dos and don'ts (see section on permitted and prohibited practices).
- Do not use laudatory language or references to medical professionals or entities.
- Rx and OTC advice must always be included.
- For OTC drugs, language must be simple and non-technical.
- Watch the use of ®, “TM”, brand name, trademarks or trade names.
- Watch for kickback arrangements involving suppliers/distributors.
- Do not enter into bribe/kickback arrangements disguised as sponsorships.
- Do not enter into agreements where there is potential ambiguity on fees and payment.
- Observe overseas anti-bribery laws such as the US Foreign Corrupt Practices Act.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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