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Global Legal Group

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2005

A practical insight to cross-border Pharmaceutical Advertising work

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

In China, advertising of medicinal products is primarily governed by the Advertising Law, the Medicine Administration Law (and its implementation rules) and the Regulations on the Administration of Medical Devices. In addition, some departmental regulations, such as the Measures on the Reviewing of Medicine Ads, the Standards for the Reviewing of Medicine Ads, the Measures on the Administration of Medical Device Ads, the Measures on the Reviewing of Medical Device Ads, the Standards for the Reviewing of Medical Device Ads, and the Measures on the Administration of Internet Medical Information Services are also relevant to the subject matters and issues covered by the above-mentioned laws.

1.2 How is "advertising" defined?

Article 2 of the Advertising Law defines "advertisement" as any form of commercial advertisement whereby merchants of regulated goods or services present, at their own cost, their products directly or indirectly in particular media or forums to prospective customers.

1.3 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Advertising of medicines, medical devices, fertilizers, and veterinary medicines on radio, TV, movies, newspapers, periodicals or other media is subject to prior review by the relevant authorities. For instance, the Measures on the Reviewing of Medicine Ads provide that the applicant must submit a completed "Advertisement Review Form", along with the following documents:

- the applicant's business license duplicate;
- the production approval certificate, quality standards, manual, and packaging of the medicine;
- the trademark registration documents of the medicine; and
- the medicine name approval certificate, etc.

Upon satisfactory preliminary review (which may be waived) and final review, the reviewing authority will issue a "Medicine Ad Approval Number" to the applicant, with a term of effectiveness is one year.

1.4 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The authorities are authorised to suspend the ads that are released in violation of law, and/or to compel the advertising company to rectify the violation and to mitigate the negative effects of the ads to a reasonable extent. They are also authorised to impose other administrative penalties.

The advertising company may file for an administrative review of the above administrative sanctions, and additionally, may institute an administrative action on the outcome of the review. It may also skip the review and institute an action against the administrative decision within certain time limits.

1.5 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The Advertising Law and relevant regulations impose fines and forfeiture of illegal profits, in addition to establishing administrative penalties such as suspension of the ads, public rectification of the violation and mitigation of negative effects. The regulations also leave open the possibilities of civil and criminal liabilities. The medicine administrations and the administrations of industry and commerce are also the administrative agencies responsible for medicine ads. In general, the advertising laws and regulations have been strictly enforced. In 2004, several cases were publicised in Beijing, Shanghai and Shandong, and other cities. In one case in Beijing which involved the release of misleading medicine ads, the advertising company was fined RMB 200,000 (approximately US$24,000). Under PRC law, violation of the aforementioned advertising laws and regulations is not a cause of action by competitors.

Nonetheless, competitors whose interests were impaired may institute an action pursuant to the Anti-Unfair Competition Law.

1.6 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

If an advertising agent misleads in promoting products, or engages in acts that impair the goodwill of a third party, the agent will be subject to fines or other penalties and the third party whose legal interests have been impaired may institute an action for damages pursuant to the Anti-Unfair Competition Law.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

Advertising Law, Medicine Administration Law and Standards for the Reviewing of Medicine Ads prohibit any "advertising" prior to the issuance of the medicine production and distribution permits. Nonetheless, the law does not ban the provision of medicinal information to health professionals. Further, discussing or releasing medicinal information through academic symposia is permitted, even symposia sponsored by medicine producers.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

The publishing of medicinal information, prior to the issuance of the production permit, is permitted, provided that the information is only published in academic journals. Speaking through academic symposia is a permitted form of publishing.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

The Advertising Law and the relevant regulations prohibit the issuance of press releases which are in effect ads. Nonetheless, the law does not explicitly prohibit press releases prior to the issuance of medicine production permits. This is, however, a strictly regulated practice - for example, news releases regarding efficacy and target patient groups for drug products are prone to be treated as ads and therefore may subject advertisers to administrative penalties. However, according to the Medicine Administration Law, limited pre-market information regarding prescription medicines may be presented in or distributed through certain medical or pharmacological journals jointly designated by the health administrations and medicine administrations under the State Council, with the general understanding that marketing activities targeted at the general public through mass media ads or other promotional forums are strictly prohibited.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Under special circumstances medicine producers may, prior to the issuance of production permits, provide unsolicited medicinal information directly to health professionals. According to the Provisions on the Administration of Medicine Clinical Trials issued by the State Food and Drug Administration, pharmaceutical or biologics firms promoting their clinical-stage products must provide certain underlying scientific data and information regarding their products whenever such firms distribute information on an unsolicited basis.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Medicinal information can be provided to medical institutions for specific purposes, such as providing pricing information, to enable institutions to develop procurement budgets. Such information cannot be provided as a means for distributing "disguised" advertising in violation of the Advertising Law, Medicine Administration Law, and the Measures on the Administration of New Medical Device Products.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

The Advertising Law and other relevant laws and regulations do not identify specific information that must appear in ads directed to health institutions or professionals. However, as a general rule, if an ad contains such information as the functionality, place of production, therapeutic use, quality, price, producer, expiration date and warranties, such information must be clear and unambiguous.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in your country?

Comparator ads are governed by the Advertising Law and Anti-Unfair Competition law. The advertising company, ad producer and publisher shall not engage in unfair competition in the process of advertising. According to Article 14 of the Advertising Law, drug product and medical device ads may not contain any information comparing the efficacy or safety of a competitor's drug products and/or medical devices. Likewise, the Standards for the Reviewing of Medical Device Ads issued by the State Administration in Industry and Commerce in 1995 ban medical device ads that defame a competitor's products, or compares the efficacy or

safety of such products with other medical devices. Furthermore, products that are not yet permitted to be marketed in the PRC cannot be used as a basis of comparison in ads.

3.3 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

Teaser ads are not prohibited under PRC law. Nonetheless, the Advertising Law provides that, as a general rule, ads must be distinctive, that is, they must be discernible by consumers as ads. If an ad contains information such as functionality, place of production, therapeutic use, quality, price, producer, expiration date and warranties (in the case of service ads, the scope, form, quality, price and warranties provided by the service), such information must be clear and unambiguous.

4 Gifts and Financial Incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

Restrictions on samples are typically found in the regulations governing clinical trials of new medicines conducted through clinical research organisations or other similar institutions. Making available free samples, medicines and medical devices to medical institutions is not subject to extensive restrictions. Notwithstanding this, for clinical trials of medical devices, no ads may be released, and further, medicine producers may not provide new medicines directly to institutions or clinical doctors for clinical trial.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

According to the Medicine Administration Law, medicine producers and distributors may not give, and likewise medical institutions may not take, off-the-book kickbacks or other interests (things of value). Medicine producers, distributors or their agents may not give gifts or other interests to officers, medicine outsourcing staff and doctors of the purchasing institutions on any account whatsoever. Furthermore, the officers, medicine outsourcing staff and doctors of such institutions may not take gifts or other interests given by medicine producers, distributors or their agents on any accounts whatsoever.

Several Provisions on Anti-Unfair Competition in the Medical Industry also explicitly prohibit medicine producers and distributors from inducing institutions to purchase their products through cash, gifts, trips, fee reimbursements, etc.

However, medicine producers and distributors are permitted to provide sale discounts to buyers, with the understanding that any such discounts must be treated and booked as such for accounting purposes. Likewise, buyers who take discounts without properly accounting for such discounts are deemed to have committed bribery.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

According to the PRC Law on Non-Profit Donations, non-profit organisations and institutions may receive donations. With respect to donations to hospitals, the rules are not well defined, whereas the Provisional Rules on the Donation of SARS-Preventive Medication and Medical Devices issued by the State Food and Drug Administration provide for the testing and acceptance procedures in the donation of overseas-produced medicines and medical devices. To cite some of the rules, the overseas-produced medical devices that can be donated must be certified as approved "Imported Medical Devices" or alternatively, considered "quality products" whose marketing has been approved overseas. For products that are not certified "Imported Medical Devices" but whose marketing has been approved overseas, the beneficiary must provide the product quality warranty or quality certification, and the product liability statements of the donor and beneficiary. If the products do not come with Chinese labels, the beneficiary must provide Chinese manuals at the time of the delivery of the products.

Further, the following medicines and medical devices cannot be donated:

a) medicines not approved by the State Food and Drug Administration;

b) medical devices for which a Medical Device Registration Certificate has not been issued;

c) overseas-produced medicines and medical devices whose marketing has not been approved overseas;

d) medicines approved by the State Food and Drug Administration only for clinical trial or trial production; medical devices approved by the State Food and Drug Administration only for clinical trial or clinical testing;

e) hospital preparations;

f) bio-products produced overseas; and

g) medicines produced according to local standards of its place of production that had subsequently been replaced and strengthened.

4.4 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

According to the Anti-Unfair Competition Law, distributors are permitted to provide volume-related discounts as well as commissions to intermediaries or brokers involved in sale transactions. Such discounts and commissions must be properly accounted in the books and records of both the distributor and the party receiving the discount or commission. Payments of cash or other bribes for purposes of inducing an institution to purchase medicinal products is, as one would imagine, strictly prohibited.

Identical rules are found in the Several Provisions on Anti-Unfair Competition in the Medical Industry.

4.5 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

PRC law is silent on this issue. It is our view that this practice is permissible, insofar as it does not go beyond the limits of the law to the extent of constituting unfair competition. For example, a distributor may not engage in below-cost sales to pre-empt market competition.

4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

According to the Standards for the Reviewing of Medical Device Ads and Standards for the Reviewing of Medicine Ads, ads shall not contain such wording as "refund if ineffective", or "product insured" etc. For purpose of this rule, prescription medicine products are treated the same as over-the-counter medicine products.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

PRC law does not explicitly prohibit entertaining health professionals. However, existing rules and regulations provide that entertaining should be provided with some restraints, especially with respect to any activities that may have the effect of influencing the medical practice of a health professional. In particular, several provisions on Anti-Unfair Competition in the Medical Industry prohibit medicine producers and distributors from inducing medical institutions or professionals into buying their products with the aid of cash, gifts, trips or fee reimbursements.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

In this respect, the answer to question 5.1 applies here, as well. That is, although the law does not explicitly prohibit this practice, such payments may only be provided with some restraints.

5.3 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Health professionals may be compensated for their expert services. According to the Provisions on the Administration of After-Work Services and Part-Time Jobs by Health Professionals, physicians and other health professionals are permitted to engage in after-work services or part-time jobs, the former including out-patient services, operations, physical check-ups, teaching and consulting services etc, and the latter referring to the taking up, by professionals with middle or upper middle professional titles, of part-time compensated professional jobs with other institutions, such as medical practice, teaching or research, etc. Compensation for such part-time activities may not, however, include any "referral fees", kickbacks, or "complimentary fees". In addition, the part-time activities may not take up more than 2 working days per week.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Subject to the approval of the provincial-level medicine administrations where the drug producer resides and upon the issuance of the Medicine Ad Approval Number, non-prescription medicines (or "over-the-counter" drugs) can be advertised in mass media outlets. According to the Medicine Administration Law and the Advertising Law, any such ads must be truthful, legal and consistent with the manuals approved by the medicine administrations under the State Council. The ads must not be misleading or contain false information, or unscientific claims or warranties with respect to efficacy. Furthermore, no substantiation shall be provided in the name of government agencies, medical or pharmacological research institutes, academic institutes or experts, scholars, medical practitioners or patients, nor supported by the images thereof.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

The Medicine Administration Law prohibits the dissemination of prescription medication ads in the mass media or the promotion of prescription medication to the general public. However, prescription medicine products may be publicised in certain medical or pharmacologic journals jointly designated by the health and medicine administrations under the State Council.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Yes, disease awareness campaigns are permitted, provided that they are within the limits of the law. For example, the Circular on Banning Illegal Medical Practice by Medicine Retailers issued by the Ministry of Health on December 5, 2001 explicitly forbids medical retailers from engaging in medical practice in the guise of "free out-patient services" or "medical consulting", or otherwise promoting medicines or medical devices. Therefore, in the circumstances where practicing is allowed, the bottom line is the practitioner may not refer to or mention specific medications, or advise the public on taking certain medications under certain circumstances, otherwise the practice will be deemed as disguised advertising and therefore be banned.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

The Medicine Administration Law provides that press releases relating to prescription medications may only be distributed through certain medical or pharmacological journals jointly designated by the health and medicine administrations under the State Council. Therefore, advertising of prescription medicines in the form of press releases included in non-science journals is strictly prohibited.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

In general, Internet-based advertisement is governed by the Advertising Law and the relevant regulations. To the extent that the Measures on the Administration of Internet Information Services mandate the administrative approval of Internet-based distribution of information services in health care, medicines or medical devices, such services must be approved by the authorities before a service provider may proceed with applying for a business and/or operating license. In addition to the Advertising Law and the above-described Measures, the State Food and Drug Administration recently issued the Measures on the Administration of Internet Medicine Information Services (introduced in 2004) to regulate Internet medicine information services. It can thus be said that Internet-based advertising is a regulated sector.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

There are no explicit rules in this respect. At present, websites under operation in China that target medical professionals are mostly membership-based. That is, only their members, after having registered to use such websites, may view and access information on the websites.

Beyond practical limitations, the Provisional Rules on the Administration of Internet Medicine Information Services have established certain minimum qualifications for Internet medicine information service providers, together with providing the procedures for obtaining such qualifications. Under these provisional rules, Internet medicine information service businesses are divided into two categories: for-profit and non-profit services. The provisional rules also explicitly provide that Internet medicine information service businesses and e-commerce sites must be approved by the State Food and Drug Administration.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

The advertising of medical devices is governed primarily by the Advertising Law, the Provisions on the Administration of Medical Devices, the Measures on the Review of Medical Device Ads, the Standards for the Review of Medical Device Ads, the Measures on the Administration of Medical Device Ads, and other administrative regulations.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

According to the Anti-Unfair Competition Law, merchants may not buy or sell merchandise with the aid of giving cash, gifts or other bribes. Off-the-book kickbacks are deemed bribery. Therefore, medical device producers and distributors may not give kickbacks or other interests to medical institutions or professionals for the purpose of promoting medical devices.

Similar provisions are found in Several Provisions on Anti-Unfair Competition in the Medicine Industry.

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HOGAN & HARTSON LLP

Founded in 1904, Hogan & Hartson LLP is the oldest and the largest major law firm based in Washington, D.C. Today, it has close to 1,000 lawyers serving clients in a practice that cuts across virtually all legal disciplines. Hogan & Hartson LLP established its China offices in Beijing in August 2002 and Shanghai in October 2004. The lawyers and legal professionals resident in Beijing and Shanghai have received their training and qualifications in the United States, China and England and have represented multinational and Chinese clients engaged in a broad range of commercial transactions and regulatory issues since the 1980s. Among the particular strengths of the China offices are cross-border mergers and acquisitions, joint ventures and other investments, financings, infrastructure development and company restructurings; government regulation, regulatory matters involving food, pharmaceuticals and medical devices, commercial transactions and intellectual property. Our office's professional staff advises international clients on structuring investments and operations throughout China, and in dealings with the Chinese regulatory bodies. In addition, we counsel Chinese companies and Chinese government ministries on a broad range of matters, including outbound investments, identification of partners and trade issues.

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