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Global Legal Group

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

Published by Global Legal Group with contributions from:

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in the People's Republic of China?

The main pieces of legislation governing advertisement in the People's Republic of China ("PRC") are as follows:

- the *Advertising Law of the People's Republic of China* ("**Advertising Law**"), effective from February 1, 1995 (Article 14 - Article 17 of which specifically set out the rules governing advertising of medicinal products and medical device);
- the *Regulations on Administration of Advertisements*, effective from December 1, 1987; and
- the *Detailed Implementing Rules for the Regulation on Advertising*, amended in 2004.

Further, the PRC State Administration for Industry & Commerce ("**AIC**") amended and issued in 2004 the new *Measures for the Administration of Advertising on Printed Matters* which are applicable to print advertisements. All of the above laws and regulations govern the advertising of medicinal products.

The advertising of medicinal products is also governed by the following laws and regulations:

(a). *Law of the People's Republic of China for the Administration of Pharmaceuticals*, adopted on September 20, 1984 and amended on February 28, 2001 ("**Pharmaceutical Law**");

(b). the *Implementing Regulation of Pharmaceutical Administration Law of the People's Republic of China*, promulgated by State Council on August 4, 2002 ("**Pharmaceutical Implementing Regulation**");

(c). *Standards for the Examination and Publication of Drug Advertisements*, effective from May 1, 2007 ("**Drug Advertisements Standards**");

(d). *Measures for the Examination of Drug Advertisements*, effective from May 1, 2007 ("**Examination Measures**"); and

(e). *Measures for the Administration of Drug Information Service over the Internet*, effective from July 8, 2004 ("**Internet Measures**").

State Food and Drug Administration ("**FDA**") and State AIC, which are the main governmental departments responsible for matters relating to advertising of medicinal products, also publish administrative notices or promulgate administrative regulations relating to advertising of medicinal products from time to time, e.g. *FDA's Notice on Proper Use of Drug Names in Advertisements of Pharmaceuticals*, *FDA's Notice on Establishment of Publishing System of Illegal Advertisements of Pharmaceuticals*, etc. Also, advertising of medicinal products is subject to various local regulations issued by local governments.

All advertisements of medicinal products need to be pre-approved by the government (i.e. the provincial level FDA).

1.2 How is "advertising" defined?

"Advertising" is defined in the Advertising Law as an act involving a business operator directly or indirectly introducing its products or services at its own expense, through a certain medium and in a certain form. According to *Measures for the Administration of Advertising on Printed Matters*, print advertisements refer to the common forms of print advertisements, such as leaflets, posters, and brochures by which an advertiser publicises by himself or entrusts an advertising business operator to issue to promote relevant commodities and services, or print advertisements in a fixed form such as specialised publications with fixed names, specifications, and patterns by which an advertising operator issues to promote relevant commodities and services. According to the Examination Measures, the term "Pharmaceutical Advertisement" refers to all advertisements which are published through various media or in various forms and contain drug names, indications or other drug-related contents. All advertisements of medicinal products need to be pre-approved by the government (i.e. the provincial level FDA).

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

The law does not prescribe specific arrangements that companies must have in place to ensure legal compliance. However, companies should adopt internal procedures and systems to ensure that the contents of their advertisements comply with legal requirements. Further, all advertisements of medicinal products need to be pre-approved by the government (i.e. the provincial level FDA).

1.4 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 medicinal products in China is subject to prior review and approval by the provincial level FDA.

The approval procedures are as follows:

(a) a properly licensed manufacturing enterprise or, upon the consent of the manufacturing enterprise, trading enterprise of the medicinal product, or its authorised agent, would apply to obtain a "drug advertisement licence number" ("**Ad Licence**") by submitting an Examination Form of Advertising Medicinal Products ("**Examination Form**") and relevant documentary evidence to the provincial FDA of the place where the manufacturing enterprise of the medicinal product is located; an application for the Ad Licence of an import drug would be submitted to the provincial FDA of the place where the Chinese agent of the import drug is located;

(b) the provincial FDA would issue a Notice of Acceptance if the application documents are complete and satisfy legal requirements. If the application documents are not complete or fail to satisfy the legal requirements, the provincial FDA would notify the applicant of the necessary amendments requiring the applicant to make immediately or within 5 working days;

(c) within 10 working days from the day of acceptance of the application for approval, the provincial FDA would examine the authenticity, legality and validity of the documentary evidence submitted and examine the content of the advertisement according to law. If the drug advertisement passes the examination, the provincial FDA would issue the Ad Licence and the advertisement may be placed for publication; otherwise, it would make a decision of refusal, notify the applicant of the decision in writing with reasons, and, notify the applicant of its right to apply for an administrative review or bring an administrative lawsuit according to law; and

(d) for all approved advertisements, the provincial FDA would report to the SFDA for record and send the approved Drug Ad Examination Form to the provincial AIC for record.

Where an advertisement of medicinal products is to be published outside of the place where the manufacturing enterprise of the drug or the import drug agency is located, after obtaining approval as discussed above, recordal of the approval should be made with the provincial FDA of the place where the advertisement is to be published.

The validity period of an Ad Licence is one year.

1.5 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?

Yes. FDA and AIC have the power to stop the further publication of a previously approved advertisement of medicinal products if it is later found to be in contravention of the Advertising Law, Pharmaceutical Law, Pharmaceutical Implementing Regulation, Examination Measures, etc.

For an offending medicinal product advertisement which intentionally exaggerates the indications, exaggerates the curative effects by using absolute terms and misleads in material respect, the local AIC at or above the provincial level should take administrative measures to suspend the distribution of the product within its jurisdiction and, at the same time, order the enterprise which publishes the drug advertisement to issue a notice of correction in the corresponding local media.

According to Article 48 of the Advertising Law, an administrative review with the next higher level authority may be sought within 15 days from the date of receipt of the notice of punishment. A case may also be directly brought before the people's court within 15 days from the date of receipt of the notice of punishment.

1.6 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 liabilities for failing to comply with the rules governing the advertising of medicines include administrative, civil and criminal liabilities. FDA and AIC are the enforcement authorities for administrative penalties, courts are the enforcement authorities for civil liabilities, and the public security bureaux, the prosecutors and the courts are the enforcement authorities for criminal penalties.

Administrative penalties include stopping the publication of the advertisement, confiscation of the advertising incomes, imposition of fines, revocation of the Ad Licence, refusal to accept application for Ad Licence for one year or three years, publication of a blacklist of the names of the offending companies and details of the offending advertisement on the websites of FDA and AIC, etc. For offending advertisements which intentionally exaggerate the indications, exaggerate the curative effects by using absolute terms and mislead in material respect, the local AIC at or above the provincial level should take administrative measures to suspend the distribution of the drug within its jurisdiction and, at the same time, order the offending enterprise to publish a notice of correction in the corresponding local media.

Civil liabilities include injunction, compensation and public apology.

The criminal liabilities are set out in Article 222 of PRC Criminal Law. According to Article 222 of PRC Criminal Law, where, in violation of State regulations, an advertisement owner, advertising agency, or advertisement carrier gives false information through advertising, and when the circumstances are serious, the offender should be sentenced to not more than two years of fixed-term imprisonment or criminal detention, and/or issued a fine.

There have been many instances where the administrative authorities, i.e. local FDAs and AICs, enforce against pharmaceutical companies for advertising violations, including issuing injunctions and fines against the companies for placing advertisements which were previously approved by the provincial FDAs.

Competitors may take actions with the administrative authorities, courts or the criminal enforcement authorities.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self- regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The advertising industry self regulatory body in China is not very developed. It generally does not take on any assessment or enforcement role. Supervisory and enforcement functions are performed solely by the government. Government authorities have the power to investigate matters and do exercise such authority against violations

1.8 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?

PRC Anti-unfair Competition Law provides that business operators should not use advertisement or other means to make false representations in respect of the quality, composition, function, usage, producer, efficacy period and place of production of commodities, and advertising companies should not knowingly be an agent of, or design, or make, or issue false advertisement. If a business operator issues false advertisements, it would be ordered to stop, rectify, pay a fine in the range of 10,000 to 200,000 RMB (depending on the circumstances); if an advertising company knowingly uses advertisement or other means to make a false or misleading description of the relevant commodities, it would be ordered to stop, have its illegal income confiscated and pay a fine.

PRC Anti-unfair Competition Law also provides that business operators should not fabricate and spread false information to damage the goodwill or reputation of the goods of their competitors.

Both the government (e.g. FDA and AIC) or private individuals or organisations (including competitors) may take actions.

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?

A medicinal product may only be advertised after it has already obtained product registration. However, PRC laws and regulations do not prohibit the provision of scientific information to health professionals before that product is registered if no advertising is involved, e.g. merely for academic or scientific purposes and not for promotional or marketing purposes.

PRC laws and regulations do not prohibit health professionals discussing medicinal products which have not yet been registered at scientific meetings, even if the meeting is sponsored by the developer company. However, discussions should be for academic or scientific purposes only, and not for promotional or marketing purposes. Please also note that Drug Advertisements Standards strictly prohibit companies from using the name or registered trademark of a prescription drug or enterprise trade name as the title of any activity, including scientific meetings, even if the product has already been registered.

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

Information on medicinal products that have not yet been registered may be published only for scientific purposes and may not be published for promotional or marketing purposes.

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

Advertising Law prohibits publishing advertisements in the form of news report. However, if the press release includes merely academic or scientific information and no promotional or marketing information, then it is allowed.

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

Information on medicinal products which have not yet been registered may be sent to health professionals without being solicited as long as it is for scientific purposes and not for promotional or marketing purposes.

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?

Sending product information to institutions for budget purposes would be construed as marketing and promotion. Information on medicinal products which have not yet been registered is prohibited from marketing and promotion, and hence such information should not be sent to institutions for planning budgets.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Companies can involve health professionals in market research for medicinal products which have not yet been registered. However, medicinal product advertisements may not feature doctors or experts. Therefore, launch materials may not feature doctors and experts involved in the market research which generated information and data for the launch materials.

3 Advertisements to Health Professionals

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

Drug Advertisements Standards prescribe that certain information must appear in a pharmaceutical advertisement, whether such an advertisement is directed to the general public or health professionals:

(a) Ad Licence;

(b) drug production license number;

(c) the generic name of the drug;

(d) the statement "Only for the professionals of medicine and pharmacy" if the product is a prescription product, and the statement "Please purchase and use in accordance with the instructions or under the guidance of pharmacist" if the product is a non-prescription product; and

(e) the name of the manufacturer or trading enterprise of the drug.

An advertisement of a non-prescription drug should feature the government designated OTC logo.

Further, all advertisements of medicinal products need to be pre-approved by the government (i.e. the provincial level FDA).

3.2 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

Comparative advertisement comparing medicinal products as to function and safety is prohibited even if there are supporting data. Denigration of another pharmaceutical company's product is also prohibited.

3.3 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 China?

Both *Standards for the Examination and Publication of Drug Advertisements and Standards for the Examination* and *Publication of Medical Device Advertisements* prohibit comparative advertisement comparing products as to function and safety even if there are supporting data. Advertising Law prohibits denigration of another company's commodities or services.

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

Scientific papers may be distributed to doctors but pharmaceutical companies should be careful not to promote unregistered products or off-label uses of registered products.

3.5 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)?

Information distributed for the purposes of scaring up business is prohibited. Otherwise, heath information may be distributed provided advertising legal requirements are complied with. For example, if the information involves the description of certain signs and symptoms or ailment and references to new treatment methods in the pipeline, such information would be permitted. For further examples, if the information identifies the name of a product that has not yet been registered, then such information may not be advertised to the public. If the information involves the description of certain signs and symptoms or ailment and advice that concerned individuals should ask their doctors, then the information would be permitted. If the information identifies the name of a registered product, the information would also be permitted as long as other legal requirements are also complied with (e.g. the advertisement has been pre-approved by FDA). Both reminder (which merely mention the name of a registered drug and not its function) and help-seeking (which encourage individuals with a particular condition to seek advice from doctor without identifying a registered product) statements are acceptable.

4 Gifts and Financial Incentives

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

Provision of samples to health professionals licensed to prescribe the sampled drug is not prohibited. However, free samples should be avoided when selling pharmaceutical products. Gifting any prescription or non-prescription pharmaceuticals of Category A to the public through means such as tie-in sales and gifts to purchasers of pharmaceuticals or other commodities are prohibited. Further, sales of pharmaceutical products through providing gifts is prohibited.

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

Unless the gifts or donations are nominal in value, gifts or donations to doctors may have issues. According to *Law on Practicing Doctors of the People's Republic of China*, doctors are not allowed to solicit or illegally accept money or articles from patients or seek other illegitimate gains by taking advantage of their positions. The *PRC Anti-unfair Competition Law* provides that business operators may not use bribes to sell or purchase merchandise. Under the *Provisional Regulations on Prohibiting Commercial Bribery Activities* ("Commercial Bribery Regulations"), "bribery" is further defined as the "act of giving valuables or utilising other methods to bribe others for the purpose of selling or purchasing merchandise". The term "valuables" is broadly defined as cash or payment in kind, including merchandise, fees (such as sales promotion fees, advertising fees, sponsorship expenses, research fees, personal service fees, consulting fees, or the writing-off of such fees), commissions and "others". "Others" is defined as other methods for conferring benefits, such as the provision of tours, visits, etc., inside or outside of the PRC, in the guise of official trips or studies. According to the *Regulation on Prohibiting Unfair Competitions in Pharmaceutical Industry*, pharmaceutical enterprises should not use bribes, providing trips or visits, reimbursing expenses, etc., to solicit others to purchase their medicinal products. Therefore, pharmaceutical enterprises should not give gifts or donate money to doctors to facilitate the sale of their products, e.g. by the doctors writing more prescriptions for the products.

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?

Giving gifts or donating money, equipment, etc. for promoting or selling pharmaceutical products is prohibited. Medicinal products should not be sold by giving gifts. Pharmaceutical enterprises are not allowed to give gifts to institutions purchasing their products when selling the medicinal products to such institutions.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

Provision of medical or educational goods or services to doctors so that they would prescribe more pharmaceutical products of the donor companies is prohibited. However, if the medical or educational goods and services are of nominal value and they are not at all tied to prescribing patterns (e.g. the doctor changed prescribing patterns because of the scientific data he was presented with), then they would be allowed.

4.5 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?

Pharmaceutical enterprises may offer *bona fide* volume related price reductions. However, the reductions must be disclosed and properly reported.

4.6 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?

Pharmaceutical products may not be sold through providing gifts. Therefore, pharmaceutical enterprises should not offer to provide, or to pay for, additional medical or technical services or equipment contingent on the purchase of medicinal products.

4.7 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?

Offering a refund scheme is allowed if the scheme is a bona fide one aiming to compensating for damages caused to purchasers as discussed below.

According to *Law of the People's Republic of China on Protection of Consumer Rights and Interests*, consumers have the right to claim refund if a product causes damages to the consumer. According to Article 28 of Product Liability Law of People's Republic of China, sellers are responsible for repair, replacement or return of a product and for compensating damages done to end-users or consumers in any of the following circumstances:

(a). the product does not have the property for use it should have and there was no advance explanations;

(b). the quality of the product does not conform to the relevant standards or to the standards specified in the packaging; and

(c). the quality of the product does not conform to the quality specified in the product use instructions or with the quality of the samples provided.

Companies are obliged to refund purchasers if the medicinal product does not work or causes damages.

Under *Administrative Measures for Drug Recalls*, drug manufactures must voluntarily recall their products from the market if the products may have safety issues.

To avoid having a refund scheme being construed as not bona fide, the manufacturer or supplier should fully and accurately report the refund (including any free items).

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Pharmaceutical companies may sponsor continuing medical education. Companies are prohibited from using the name or mark of a prescription drug or trade name as the title of any activity, including continuing medical education courses. The contents of the event need to have substantive scientific or educational value and not just a front for extravagant entertainment of the doctors. Pharmaceutical companies should only provide financial support for travel, lodging and reasonable personal expenses. Preferably, a pharmaceutical company should avoid directly subsidising a healthcare professional. Preferably, any financial support should be provided to the event's organiser to reduce the cost of attending for all attendees. Health professionals should not receive the sponsorship money directly.

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?

The *PRC Anti-unfair Competition Law* provides that business operators should not use bribes to sell or purchase merchandise. Under the *Provisional Regulations on Prohibiting Commercial Bribery Activities* ("*Commercial Bribery Regulations*"), "bribery" is further defined as the "act of giving valuables or utilising other methods to bribe others for the purpose of selling or purchasing merchandise". The term "valuables" is broadly defined as cash or payment in kind, including merchandise, fees (such as sales promotion fees, advertising fees, sponsorship expenses, research fees, personal service fees, consulting fees, or the writing-off of such fees), commissions and "others". "Others" is defined as other methods for conferring benefits, such as the provision of tours, visits, etc., inside or outside of the PRC, in the guise of official trips or studies. Offering of hospitality to sell medicinal products or to induce health professional to write more prescriptions for medicinal products would be considered bribes, whether the hospitality is offered in or outside China.

However, companies may hold educational events with substantive scientific or educational value, although the events should not be fronts for extravagant entertainment of health professionals.

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?

Doctors are not allowed to seek illegitimate gains by taking advantage of their positions. Further, in China, most hospitals and medical institutions are owned by the State. Therefore, doctors working for such hospitals and medical institutions would also be considered "State personnel" and thus additionally subject to official bribery rules. Article 393 of PRC Criminal Law provides that anyone who gives property to State personnel in order to obtain improper benefits commits the crime of bribery. The term "giving of property" includes the provision of domestic or international travel, and the term "improper benefits" includes benefits obtained from contravening the law or from a dispensation from compliance with mandatory legal requirements. When paying for a doctor who is also a State personnel, American pharmaceutical enterprises should additionally be aware of issues under the *Foreign Corrupt Practices Act* ("**FCPA**") adopted by the United States. FCPA prohibits "issuers, domestic concerns, and any person from making use of interstate commerce corruptly, in furtherance of an offer or payment of anything of value to a foreign official, foreign political party, or candidate for political office, for the purpose of influencing any act of that foreign official in violation of the duty of that official, or to secure any improper advantage in order to obtain or retain business."

For the foregoing, sponsorship should not go to an individual doctor. The sponsorship money going to reduce the conference fees or other conference expenses for all the attendees would be acceptable if the sponsorship is not done to induce the doctor to increase purchase of medicinal products or write more prescriptions for medicinal

products. Reasonable travel expenses, accommodation expenses and enrolment fees are normally considered to be directly related to the meeting and are allowed as long as they are not paid to induce the doctors to purchase more medicinal products or write more prescriptions in respect of the relevant medicinal products. Also, it is advisable to not give money for the meeting directly to the individual doctors. For example, it is preferable to pay the enrolment fees directly to the organiser of the scientific meeting. Companies are prohibited from using the name or mark of a prescription drug or trade name as the title of any activity, including scientific meetings. Personal expenses of the doctors during the meeting but not directly related to the meeting should not be paid for on behalf of the doctors.

The doctors should not be paid for their time for attending the meetings.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

If the arrangements are too extravagant, e.g. providing golf events, expensive menus, expensive gifts, spa services, ballet, opera, and/or musical or other high end theatre tickets, the meeting may be challenged as instruments of bribery.

The contents of the meeting need to have substantive scientific or educational value and not just a front for extravagant entertainment of the doctors. Further, companies are prohibited from using the name or mark of a prescription drug or trade name as the title of any activity, including scientific meetings.

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

It is allowed to pay doctors to provide *bona fide* expert services as long as the payment is reasonable, the work relates to the doctors' expertise, and there is a legitimate need for the services. Further, the payment should not be for inducing purchase of relevant medicinal products or writing of more prescriptions for relevant medicinal products.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

It is allowed to pay doctors to take part in *bona fide* post marketing surveillance studies as long as the payment is reasonable, the work relates to the expertise of the doctors, and there is a legitimate need for the services. Further, the payment should not be for inducing purchase of relevant medicinal products or writing of more prescriptions for relevant medicinal products.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

It is allowed to pay doctors to take part in bona fide market research involving promotional materials as long as the payment is reasonable, the work relates to the expertise of the doctors, and there is a legitimate need for the services. Doctors, experts, medical institutions, medical research institutions and academic institutions and patients may not be featured in pharmaceutical advertisements even if they took part in the research which generated the data or information for the promotional materials.

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?

Under PRC laws, advertising non-prescription medicines to the general public is allowed. However, the advertisement must comply with legal requirements, e.g. the Drug Advertisement Standards.

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

According to Drug Advertisement Standards, advertisements of prescription drugs may be published only in professional publications of medicine or pharmacy jointly designated by the Ministry of Health and the State Food and Drug Administration, but may not be advertised to the general public.

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?

PRC laws and regulations do not prohibit disease awareness campaigns mentioning no medicines. The nature of the campaigns should not be promotional, and should only relate to health facts, treatment technologies, etc. Also, such campaigns should not be at odds with general PRC law, for example, the information provided in the campaigns should not be misleading to the audience.

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

If the contents of the press release are scientific without mentioning specific medicinal product name or its manufacturer, i.e. a press release about a new product for a type of condition, it should be allowed. However, if the press release identifies the product name or manufacturer, it would possibly be considered an advertisement. An advertisement of a prescription drug may not be issued to non-scientific journals and non-scientific journals would not be allowed to publish an advertisement of a prescription drug. Advertising Law prohibits issuing advertisement in the form of news report.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Corporate brochures are considered print advertisement under *Measures for the Administration of Advertising on Printed Matters*, and hence they are subject to the restrictions applicable to pharmaceutical advertisements discussed above.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The meetings and funding may not be for inducing sales of

medicinal products. If the talks and materials given out to the groups refer to specific medicinal products and manufacturers, they would need to comply with the legal requirements applicable to pharmaceutical advertisements. Donations and other supports must be properly reported.

7 The Internet

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

The rules applicable to other forms of advertising also apply to Internet advertising, including *Advertising Law, Regulations on Administration of Advertisements, Detailed Implementing Rules for the Regulation on Advertising, Law of the People's Republic of China for the Administration of Pharmaceuticals, Implementing Regulation of Pharmaceutical Administration Law of the People's Republic of China, Standards for the Examination and Publication of Drug Advertisements, Measures for the Examination of Drug Advertisements,* and *Measures Regarding the Administration of Drug Information Service over the Internet*. Also, *Regulation on Internet Information Service of the People's Republic of China* specifically applies to the act of providing information on the Internet. Further, some local governments have issued local rules or regulations applicable to Internet advertising, e.g. Interim Regulations on Internet Advertising of Beijing. Moreover, before providing information on pharmaceuticals or medical devices on the internet, prior approval by local provincial FDAs must be sought and Qualification Certificate for Drug Information Services over the Internet must be obtained.

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?

The law does not expressly legislate on this issue. It is advisable for pharmaceutical companies to put in place adequate security systems.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

The law does not expressly legislate on this issue. It is advisable for pharmaceutical companies to ensure that their sites are not instruments of violations or non-compliance by third parties.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The legal requirements are the same as those applicable to pharmaceutical advertisement discussed above. For example, PRC laws and regulations strictly prohibit directly or indirectly advertising prescription drugs to the general public. Therefore, pharmaceutical companies are prohibited from placing any promotional information of prescription drugs on their websites, although this prohibition is often violated and enforcement by law enforcement is sporadic. Also, according to the *Measures Regarding the Administration of Drug Information Service over the Internet*, the information placed by a pharmaceutical company on its own website must be scientific and accurate and comply with relevant laws and regulations. A pharmaceutical company is not allowed to publish any information on any narcotic drugs, psychotropic medicines, poisons, radioactive medicines, rehabilitation medicines or pharmaceutical preparations of medical institutions.

Moreover, before providing information on pharmaceuticals or medical devices on the internet, prior approval from the local provincial FDAs must be sought and Qualification Certificate for Drug Information Services over the Internet must be obtained.

8 General - Medical Devices

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

The main pieces of legislation governing advertisement of medical devices in the PRC is *Advertising Law of the People's Republic of China* ("**Advertising Law**", effective from February 1, 1995, Article 14 - Article 17 of which specifically set out the rules governing advertising of medicinal products, medical device, etc.), *Regulations on Administration of Advertisements*, effective from December 1, 1987, and Detailed Implementing Rules for the Regulation on Advertising, amended in 2004. Other than the Advertising Law and Regulations on Administration of Advertisements, the advertising of medical devices is also governed by the following laws and regulations:

(a) *Regulation on the Supervision and Administration of Medical Devices*, effective from April 1, 2000;

(b) *Measures for the Examination of Medical Device Advertisements*, effective from March 8, 1995;

(c) *Standards for the Examination and Publication of Medical Device Advertisements*, effective from March 3, 1995; and

(d) *Measures Regarding the Administration of Drug Information Service over the Internet*, effective from July 8, 2004.

Further, SFDA and State AIC publish notices or promulgate administrative regulations governing advertising of medical devices from time to time. Moreover, the advertising of medical devices is subject to various local regulations issued by local governments.

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

According to *Law on Practicing Doctors of the People's Republic of China*, doctors are not allowed to solicit or illegally accept money or articles from patients or seek other illegitimate gains by taking advantage of their positions. The *PRC Anti-unfair Competition Law* provides that business operators may not use bribes to sell or purchase merchandise. Under the Provisional Regulations on Prohibiting Commercial Bribery Activities ("*Commercial Bribery Regulations*"), "bribery" is further defined as the "act of giving valuables or utilising other methods to bribe others for the purpose of selling or purchasing merchandise". The term "valuables" is broadly defined as cash or payment in kind, including merchandise, fees (such as sales promotion fees, advertising fees, sponsorship expenses, research fees, personal service fees, consulting fees, or the writing-off of such fees), commissions and "others". "Others" is defined as other methods for conferring benefits, such as the provision of tours, visits, etc., inside or outside of the PRC, in the guise of official trips or studies. Payments or hospitality offered to doctors to induce purchase or use of the relevant medical devices would generally be considered "bribery".

However, companies may hold educational events with substantive scientific or educational value, although the events should not be fronts for extravagant entertainment of health professionals.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

In the past few years, China has introduced significant regulatory changes in an effort to modernise its pharmaceutical industry and bring it in line with international standards. These include reorganising the former State Drug Administration into the State Food and Drug Administration ("**SFDA**"), thoroughly amending drug regulations and implementing good manufacturing practice ("**GMP**"), enhancing intellectual property protection and changing drug import licensing. This rapidly evolving regulatory environment has inevitably led to uncertainty as both regulators and businesses struggle to understand and work within the new requirements.

Despite having various restrictions applied to pharmaceutical advertising, illegal advertising remains a major issue. China's official news agency Xinhua reported that 50,823 occurrences of illegal advertisements for drugs, medical devices and health supplements were found by the authorities in the first 10 months of 2007. Professionals in this field often criticise that the penalties for violating relevant laws and regulations in relation to pharmaceutical advertising are not severe enough to stop the illegal acts, and SFDA also frequently urges relevant governmental departments to enforce the rules relating to medical and pharmaceutical advertisements strictly. In recent years, SFDA has announced a series of measures designed to improve advertising standards, including prohibiting advertisement of certain classes of prescription drugs and issuing standards for labelling. Also, local governmental departments such as local FDAs and local AICs adopted various measures to reinforce the monitoring and supervision of pharmaceutical advertising, e.g. issuing blacklists of offending companies, launching online supervision systems, etc.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

China is expected to become the fifth largest pharmaceutical market in the world by 2010. Many pharmaceutical enterprises consider China as a large market and hence will invest much more money in pharmaceutical advertising. However, relevant laws and rules governing pharmaceutical advertising still need improvement. Recently, SFDA's Deputy Commissioner called for stringent drug regulation. Scholars and professionals in this field also urged the government to reinforce the monitoring and supervision of pharmaceutical advertisements, especially those published on the Internet. Therefore, it may be expected that the existing laws and rules governing pharmaceutical advertising will be implemented more strictly, and some new rules governing pharmaceutical advertising on the Internet may be adopted in the near future.

9.3 Are there any general practice or enforcement trends that have become apparent in China over the last year or so?

In November 2007, SFDA issued a press release, expressing its position against pharmaceutical companies hiring celebrities to advertise medicinal products. In February 2009, SFDA issued the *Notice on Reinforcing the Supervision of Medical and Pharmaceutical Advertisements Broadcasted on Radio and TV*, emphasising the issue of illegal medical and pharmaceutical advertisements and also prohibiting hiring celebrities without the qualification of medical professionals as guests on various medical or health shows. Therefore, it is gradually becoming a trend of pharmaceutical companies not to use celebrities in the advertisements of their medicinal products.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

As the EFPIA Code was issued by European Federation of Pharmaceutical Industries and Associations and only adopted by European countries, China did not amend its national laws and regulations in order to implement the EFPIA Code.

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