The Pharma Legal Handbook

Asia

Marketing, Manufacturing, Packaging and Labeling Advertising

PHARMA BOARDROOM

Marketing, Manufacturing, Packaging and Labeling Advertising

This Pharma Legal Handbook answers essential questions about the legal and regulatory environment in 8 countries.

Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.

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This chapter about Marketing, Manufacturing, Packaging and Labeling Advertising in China was published in association with:

FANGDA PARTNERS
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Fangda Partners is one of the first private PRC law firms established under China's contemporary legal system. We have over 550 lawyers serving international and domestic clients in various commercial matters through our teams in Beijing, Guangzhou, Shanghai, Shenzhen and Hong Kong. We are one of the leading full service PRC and Hong Kong commercial law firms with practices covering general corporate, merger and acquisition, private equity, capital markets, intellectual property, real estate, construction, infrastructure development, dispute resolution, banking and finance, labour and employment, dispute resolution and other important areas of legal practices.

We pride ourselves on the quality of our work. Our goal is to be the firm of choice for the most challenging transactions and most difficult legal issues in China. The two characters of the firm's Chinese name, "fang" and "da", meaning "integrity" and "open-mindedness", are a short-form mission statement of our practice.

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Mr. Shin leads the healthcare practice of the firm's corporate group. His experience in the sector includes major transactions in the sub-areas of pharmaceuticals, medical devices and medical services, as well as regularly offering advice to clients on regulatory developments in issues at the forefront of this area of law. Josh's recent experience in the healthcare area includes proposed acquisition by private equity fund of Cardinal Health's China business, Bayer's acquisition of Dihon Pharmaceuticals, Wuxi AppTec's joint venture with Mayo Clinics, exclusive commercialization/licensing arrangement of a number of drugs owned by big pharma, and the overseas IPO of a number of biotech companies. Mr. Shin is nominated as recognized practitioner for Healthcare by Chambers Asia Pacific 2019.

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MARKETING, MANUFACTURING, PACKAGING AND LABELING ADVERTISING

1. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?	Please refer to **Questions 3 and 6 of Chapter 1** (available in ***The Pharma Legal Handbook China*** and/or ***The Pharma Legal Handbook Regulatory, Pricing and Reimbursement Asia***) regarding the authorization of drugs and medical products.
2. What is the authorization process for the marketing of generic versions of these products?	Please refer to **Question 6 of Chapter 1** (available in ***The Pharma Legal Handbook China***) regarding the authorization of generic drugs.
3. What are the typical fees for marketing approval?	Please refer to **Question 4 of Chapter 1** (available in ***The Pharma Legal Handbook China***) regarding the fees for marketing approval of different products.
4. What is the period of authorization and the renewal process?	Please refer to **Question 5 of Chapter 1** (available in ***The Pharma Legal Handbook China***) regarding the fees for marketing approval of different products.
5. What are the requirements, if any, for post-approval pharmacovigilance?	The key regulation for China's ADR monitoring system is the 2011 Provisions on ADR Reporting and Monitoring. Drug manufacturers, distributors and medical institutions are required to report all serious ADRs they learn of to the competent ADR monitoring center within 15 days and non-serious reactions on a monthly basis. Drug manufacturers are required to report serious ADRs incurred abroad within 30 days through the China ADR Monitoring System.
6. Are foreign marketing authorizations recognized?	Foreign marketing authorizations are generally not recognized in China, all drugs and medical devices must be approved by the NMPA for sale in China. In certain pilot regions, such as Hainan province, foreign medical device and the small amount of medicine urgent for clinical use are allowed to be imported without obtaining marketing authorization from the NMPA and used in designated institutions for designated treatment purposes upon the permission from competent authorities.
7. Are parallel imports of medicines or devices allowed?	Current PRC laws contain no provisions that directly address the legality of parallel imports of medicines or devices. It is advisable for market participants to note the following rules in relation to parallel import:

(1) Patent. The PRC Patent Law is basically the only piece of PRC legislation that explicitly allows parallel import, article 69.1 expressly states that any use, offer for sale, sale or import of patented products or products produced through patented process which have already been sold by the patent owner or licensee does not constitute patent infringement.
(2) Trademark. In terms of trademark protection, PRC law does not explicitly address the issue of whether parallel import is allowed or not. Some court decisions have followed the principle of international exhaustion – that the first sale of the goods to a purchaser abroad exhausts the trademark right in China when certain conditions are satisfied (once the trademark rights are exhausted, the registered trademarks owner will no longer have the right to prevent the importation or distribution of the relevant goods); whilst other courts ruled that the first sale of the trademarked goods must occur within China.
(3) Marketing authorization. Notwithstanding the ambiguity of parallel import under IP related laws, it is certain that imported medicines or devices must have the necessary marketing authorizations.

Parallel import is not an urgent issue for the drug industry in China, because MNCs must participate in the tender for supplying drugs to public hospitals (which account for a majority share in China's drug market, especially for prescription drugs) through their national exclusive distributor in China, which effectively precludes any other parallel importers from supplying drugs to public hospitals. On the other hand, pharmaceutical companies can also limit or prevent parallel import by controlling the supply chain, for example, the agreements between a pharmaceutical company and its distributors may contain clauses on territorial limitations and non-competing obligations; importers in China may also request for an exclusive distribution right and ask the drug or devices manufacturers to take actions to prevent parallel import.

8. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?

ADMINISTRATIVE PENALTY AND INDUSTRY PRACTICE

According to the Anti-Unfair Competition Law, China's main regulation on unfair competition and commercial bribery, giving something of value to the below three categories of recipients in order to seek a transaction opportunity or competitive advantage will be regarded as commercial bribery: (i) employees of a counterparty to a transaction; (ii) any person that a counterparty uses to handle relevant matters; (iii) any person who can influence a transaction. The penalty for commercial bribery includes a maximum fine of 3 million renminbi and confiscation of illegal gains derived from corrupt transactions.

Furthermore, the Code of Practice on the Promotion of Pharmaceutical Products issued by the R&D based Pharmaceutical Association in China (RDPAC), which has been voluntarily adhered to by member pharmaceutical companies as the general baseline practices for drug promotion in China, specifically stipulates the following requirements:

- Healthcare professionals shall not generally be paid in cash and gifts for personal benefit.
- Sponsorship is only allowed for events with the purpose to provide scientific or educational information, which must be held in an appropriate venue that is conducive to such purpose.
- To engage healthcare professionals as consultants or to perform other services, a written agreement must be prepared in advance to specify the basis for payment, which shall be reasonable and in accordance with the fair market value.

CRIMINAL PENALTY

The provision of bribery may also constitute a criminal crime (official bribery or commercial bribery).

Official bribery is the criminal offence of giving, accepting, soliciting or introducing a bribe to or by state functionaries. If the offeror is an individual and the recipient is a government related entity, such as a government agency or state-owned enterprise, the threshold for prosecution is RMB 100,000; if the offeror is a legal entity, the threshold for prosecution is RMB 200,000 regardless of whether the recipient is an individual or not.

Commercial bribery includes giving a bribe and accepting a bribe. Here, none of the parties involved is government related. With respect to the crime of giving a bribe, the threshold for prosecution is RMB 60,000, if the offeror is an individual, and RMB 200,000, if the offeror is an entity. The threshold for prosecution of the crime of accepting a bribe is RMB 60,000 regardless of whether the offeror is an individual or not. Accepting a bribe by a private-owned entity shall not constitute a criminal offense.

9. How is the manufacturing of medicines and devices regulated and by which agencies?

The manufacturing of medicines and devices is regulated by NMPA and the manufacturing process should be conducted in conformity with China's Good Manufacturing Practices (GMP).

10. Are local manufacturing requirements compatible with Good Manufacturing Practices (GMPs) as defined by the US Food & Drug Administration (US FDA) and/or the European Medicines Agency (EMA)?

Most of China's current Drug GMP provisions are compatible with the GMP provisions of the United States but have its own characteristics as well. According to the Agreement between the Department of Health and Human Services of the United States of America and the State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices, entered into on December 11, 2007, the two countries agree to develop through the Work Plan details of collaboration on the establishment of internationally-recognized standards. These standards may include the ICH Guidelines, including ICH Q7A Current Good Manufacturing Practice Guideline for APIs.

11. What is the inspection regime for manufacturing facilities?

Regular or surprise inspections may be conducted by NMPA or its local counterparts during the whole drug manufacturing process, including: (i) set-up