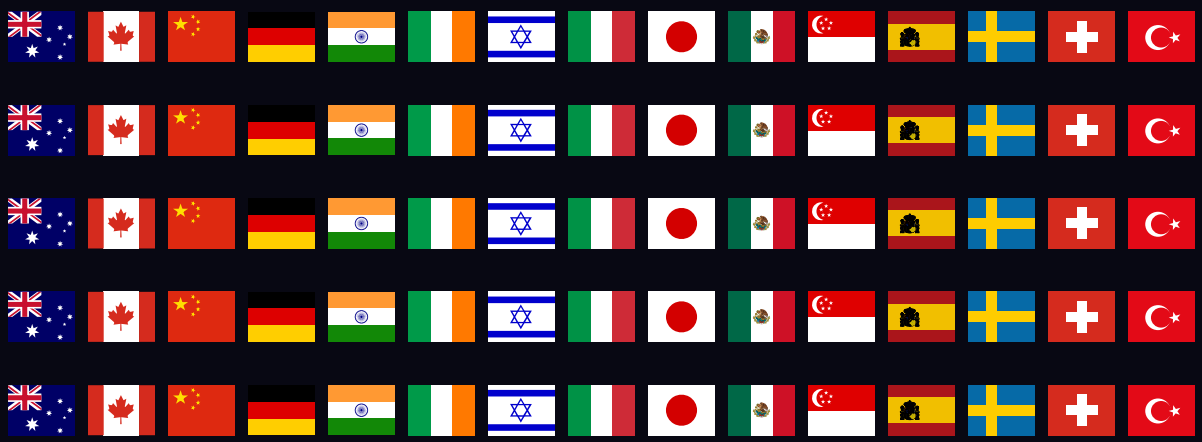
LIFE SCIENCES

China



LEXOLOGY
Getting The Deal Through

Life Sciences

Quick reference guide enabling side-by-side comparison of local insights, including into organisation and financing; authorisation of providers; advertising; data protection, privacy and digitisation; collaboration with healthcare professionals and patient organisations; competition law; pricing and reimbursement; and recent trends.

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Contributors

China

Cindy Hu
cindyhu@east-concord.com
East & Concord Partners

Jason Gong
jianhua_gong@east-concord.com
East & Concord Partners

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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

In China, the State Council and local governments at all levels lead medical care and health promotional work. The National Health Commission is a department of the State Council responsible for the overall coordination of national medical care and health promotional work. Other relevant departments of the State Council take charge of the related work within their respective responsibilities. Laws and rules regulate almost the entirety of the healthcare sector, including areas such as medical institutions, medical personnel (including doctors and nurses), pharmaceuticals and medical devices, and medical insurance.

The primary laws and regulations that apply to the healthcare sector include:

- Law of the People's Republic of China on Basic Medical Care and Health Promotion: China's first basic but comprehensive law in the field of health care, covering all aspects such as basic medical and health services, medical and health institutions and personnel, drug supply, health promotion, financial support, supervision and management;
- Drug Administration Law of the People's Republic of China and its implementation regulations: these regulate drug research and development, manufacturing, distribution and use, as well as the supervision and management of the above activities;
- Administrative Regulations on Medical Institutions and its implementation rules: these regulate the planning, layout, establishment approval, registration, practice, supervision and management of medical institutions;
- Regulations on Supervision and Administration of Medical Devices (Revision 2021): these regulate the research and development, manufacturing, distribution and use of medical devices, as well as the supervision and management of the above activities;
- Physician Law of the People's Republic of China: this regulates the examination and registration, rules of practice, assessment and training, and legal responsibilities of licensed doctors; and
- Regulations on Nurses: these regulate the registration of nurses and their rights and obligations, as well as the duties and legal responsibilities of medical institutions.

Law stated - 30 September 2022

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

The costs of basic medical services in China are mainly paid by the basic medical insurance fund and the individuals concerned. Citizens have the right and obligation to participate in basic medical insurance according to law. Pursuant to national regulation, both employers and employees pay basic medical insurance premiums for employees, while non-employees pay the premiums themselves under the category of urban and rural residents.

Medical treatment and hospitalisation expenses incurred from, for example, drugs, diagnosis and treatment, medical service facilities, emergency and rescue, if covered by the basic medical insurance, are then paid from the insurance fund in accordance with national regulations. The portion of the medical expenses paid by the basic medical insurance fund is settled directly by the insurance agency with the medical institutions and the drug distributors.

Commercial medical insurance is also part of the medical security system and is voluntary for employing entities and individuals. Commercial medical insurance is sold by commercial insurance companies. The insured person pays a certain amount of premium according to the insurance contract. When the insured suffers an illness, accident or injury

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that incurs medical expenses and loss of income, the insurance company compensates them at an agreed amount. Commercial medical insurance is a supplement to basic medical insurance.

Law stated - 30 September 2022

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

In China, basic medical services are provided mainly by public hospitals (non-profit medical institutions) established by the government and supplemented by for-profit hospitals run by private entities.

Over the past decade, the number of consultations in public hospitals accounted for about 85 per cent of the total, and the number in private medical institutions accounted for about 15 per cent. The expenses of basic medical services are mainly paid from the basic medical insurance fund, while the costs of for-profit hospital services are mainly self-paid by patients or through commercial insurance purchased by them.

Law stated - 30 September 2022

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

To set up a medical institution, one should first apply to the Health Commission at or above the county level and obtain an approval for the establishment.

Second, one should register with the appropriate registration authority (such as the Market Supervision Administration, the Registration Administration of Public Institution or the Civil Affairs Administration), depending on the legal entity type of the medical institution.

Third, one should obtain a medical institution practising licence issued by the competent health committee.

The main relevant laws and regulations include the Administrative Regulations on Medical Institutions, the Rules for Implementation of the Administrative Regulations on Medical Institutions and the Provisional Measures for the Administration of Medical Institutions in the Form of Sino-foreign Equity or Contractual Joint-Venture and its supplementary provisions.

Law stated - 30 September 2022

Structure

Which types of legal entities can offer healthcare services?

The sponsors of medical institutions can be governments, public institutions, enterprises, social groups and other social organisations, as well as individuals. The Rules for Implementation of the Administrative Regulations on Medical Institutions classifies medical institutions into 14 categories, which mainly include hospitals, maternal and child care centres, community health centres or service stations, township or neighbourhood health centres, sanatoriums, outpatient clinics, dispensaries, emergency centres, clinical testing centres, specialist disease prevention and treatment centres, and nursing homes.

Law stated - 30 September 2022

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Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

In China, there are clear restrictions on access to the healthcare industry, such as the qualification of the investor and the total investment amount with regard to foreign investment. According to relevant regulations, qualified investors from Hong Kong, Macao and Taiwan can invest for wholly-owned hospitals in pilot areas, while other foreign investors can only invest in the medical industry in the form of joint ventures, and their shareholding ratio should not exceed 70 per cent. Moreover, both parties to the joint venture should have investment and management experience in the medical industry and should meet one of the following requirements:

- be able to share international advanced management experience, management and service models of medical institutions;
- be able to provide international leading medical technology and equipment; or
- be able to supplement or improve local medical service capacity, medical technology, funds and medical facilities.

The Sino–foreign joint venture medical institution to be established must be an independent legal person; the total investment amount should not be less than 20 million yuan; and the term of the joint venture should not exceed 20 years.

Law stated - 30 September 2022

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

The main applicable laws and regulations are the Drug Administration Law of the People's Republic of China, the Advertising Law of the People's Republic of China and the Interim Measures for the Administration of Internet Advertising.

Law stated - 30 September 2022

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

At present, the applicable laws and regulations in China governing the advertising of medicinal products do not distinguish advertisements aimed at healthcare professionals from those aimed at the general public. However, prescription drugs can only be advertised in medical and pharmaceutical journals designated by the competent authority, and advertisements for prescription drugs should prominently state: ‘This advertisement is for medical and pharmaceutical professionals only’.

Law stated - 30 September 2022

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Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

Yes, the regulation of medical device advertising is as rigorous as that of pharmaceutical advertising, as the same rules apply to both.

Law stated - 30 September 2022

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

At the national level, on 27 May 2021, the National Bureau of Statistics issued the Statistical Classification of the Digital Economy and its Core Industries (2021), which defines the basic scope of the digital economy in terms of 'digital industrialisation' and 'digitalisation of industries', and explicitly covers 'intelligent medical care' (ie, medical examination, testing and imaging taking advantage of digital technology and IT platforms), as well as online medical treatment and telemedicine services.

In addition, China has formulated regulations and policies in the field of remote diagnosis and treatment, internet drug sales, personal medical data protection, and the collection, storage and application of medical big data, and these are all in the process of being continuously improved.

Personal privacy protection and data security are the core legal issues in digital health. In addition, the monopoly of healthcare data, the liability for medical damage caused by medical AI, and the ethical risks brought by the application of AI diagnosis and treatment technology are also common legal issues in digital health.

Law stated - 30 September 2022

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

The main applicable regulations on digital medical services are the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation), the Measures for the Administration of Internet Hospitals (for Trial Implementation) and the Specifications for the Administration of Remote Medical Services (for Trial Implementation). According to these regulations, online medical treatment services should be provided by medical institutions with appropriate qualifications, and the scope of online diagnosis and treatment is limited to carrying out follow-up consultations for some common and chronic diseases and signing contracts with the family doctor through the internet. Patients can obtain electronic prescriptions through online diagnosis and treatment. If only internet health consultations and health management services (not involving e-prescription and disease diagnosis) are provided, the foregoing regulations do not apply.

Law stated - 30 September 2022

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Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

Laws and regulations on data and privacy protection are generally enacted by the Standing Committee of the National People's Congress, while normative documents are usually formulated by the National Health Commission, the State Administration for Market Regulation and the National Standardization Management Committee. The Office of Cyberspace Security Commission, the Ministry of Industry and Information Technology, the Administration for Market Regulation and the Public Security Bureau at all levels are generally the enforcement agencies for data or privacy infringement cases. China is continuously strengthening and improving its legislation on data and privacy protection. The Civil Code, the Data Security Law and the Personal Information Protection Law were published in the last two years. Other related laws or regulatory documents include the Cybersecurity Law, the Electronic Commerce Law, the Measures for the Administration of Population Health Information (for Trial Implementation), the Personal Information Security Norms, the Guidelines for Big Data Security Management and the Basic Requirements for Graded Protection of Cyber Security. Specific guidance or rules issued on data protection and privacy in the healthcare sector include the Guiding Opinions on Promoting and Regulating the Application and Development of Health and Medical Big Data and the Management Measures for the Health, National Medical Big Data Standards, Security and Services (for Trial Implementation) and Information Security Technology – Guide for Health Data Security.

Law stated - 30 September 2022

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

With respect to data protection and privacy, the following basic requirements are imposed on healthcare providers:

- data collection: data collection channels should be legal and the collection of data should be authorised by patients; data collection should conform to the principle of minimum necessity and a system to protect personal medical data should be in place;
- data storage: this storage should meet the hardware requirements and implement classification protection and storage of data to be authorised by the state; and
- data analysis and application: healthcare providers should operate and use data in line with national and local government authorisations and strictly carry out data desensitisation and ensure data use is traceable.

China has no specific regulations on data protection officers or other qualified personnel.

Law stated - 30 September 2022

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

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Common infringements include collecting, storing, using and selling patients' medical information without consent, and illegally disclosing patient information.

Law stated - 30 September 2022

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

At present, China has no specific law governing the collaboration of the pharmaceutical industry and healthcare professionals. However, the collaboration should comply with, for example, anti-commercial bribery and drug advertising restrictions incorporated in laws or regulations such as the Anti-Unfair Competition Law of the People's Republic of China, the Code of Ethics for Chinese Physicians, the Drug Administration Law of the People's Republic of China and the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes.

The same rules apply to physicians in the outpatient and inpatient sectors.

Law stated - 30 September 2022

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

According to the Drug Administration Law of the People's Republic of China, it is forbidden for drug marketing authorisation holders (MAHs) (referring to entities such as enterprises or drug development institutions that have obtained drug registration certificates), drug manufacturers, drug distributors or medical institutions to give or receive kickbacks or other improper benefits in the purchase and sale of drugs.

Drug MAHs, manufacturers, distributors or agents must not grant goods or other improper benefits in any name to the persons in charge of medical institutions, drug procurement personnel, physicians, pharmacists and other relevant personnel purchasing the drug. It is forbidden for the persons in charge of medical institutions, drug procurement personnel, physicians, pharmacists and other relevant personnel to accept any goods or other improper benefits in any name from drug MAHs, manufacturers, distributors or agents.

In addition, the content of drug advertisements must be truthful, legal, without false information and in line with the drug specifications sheet approved by the drug regulatory authority. Drug advertisements must not contain assertions or guarantees of effectiveness or the safety of the drug; and must not use the name or image of state organs, scientific research entities, academic institutions, industry associations, experts, scholars, physicians, pharmacists and patients, etc for recommendation or certification. Drug advertisements must be reviewed and approved by the market regulatory authority, and they will be allocated an advertising approval number.

Law stated - 30 September 2022

Collaboration with patient organisations

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What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

Patient organisations in China currently cover a wide range of diseases, including tumours, neurological diseases, blood diseases, rare diseases and others. China has yet to develop rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations.

Law stated - 30 September 2022

Common infringements

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The most common infringements committed by pharmaceutical manufacturers regarding collaborations with healthcare professionals are violations of anti-commercial bribery and drug advertising provisions of related regulations.

If a drug MAH, a drug manufacturer, a drug distributor or agent grants goods or other improper benefits to the persons in charge of medical institutions, drug procurement personnel, physicians and pharmacists, etc, that purchase its drugs, he or she will be subject to the confiscation of the illegal income and a fine by the market regulatory authority; where the circumstances are serious, the business licence of the drug MAH, the manufacturer or the distributor will be revoked and, in addition, the drug approval documents, the drug production licence and the drug distribution licence will also be revoked by the drug regulatory authority.

Drug advertisements violating relevant regulations may be subject to administrative penalties such as orders to stop advertising, fines or the revocation of their business licence.

Law stated - 30 September 2022

Collaboration on medical devices

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

Regarding the collaboration of manufacturers of medical devices with healthcare professionals, there are no explicit restrictions on anti-commercial bribery similar to those in the pharmaceutical sector. However, medical device manufacturers must abide by the provisions on the advertising of medical devices in the Regulations on the Supervision and Administration of Medical Devices. Medical device advertisements should be truthful, legal and without false, exaggerated or misleading content. The advertisements shall be reviewed and approved by the market regulatory authority and the drug regulatory authority where the manufacturer is located and granted advertising approval numbers. In addition, medical device manufacturers must not bribe healthcare professionals to seek trading opportunities or competitive advantages, otherwise they may risk being identified as engaging in unfair competition.

China has yet to establish rules and principles applying to the collaboration of manufacturers of medical devices with patient organisations.

Law stated - 30 September 2022

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COMPETITION LAW

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

Yes. According to the Anti-Unfair Competition Law of the People's Republic of China, if a business operator engages in unfair competition such as commercial bribery, making false or misleading commercial publicity, issuing false advertisements, infringing on trade secrets, or damaging competitors' goodwill or a product's reputation, then the supervisory inspection authority will confiscate the illegal gains and impose a fine, which is generally between 100,000 and 3 million yuan. If the circumstances are serious, the business licence will be revoked.

Law stated - 30 September 2022

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Yes. According to the Anti-Unfair Competition Law of the People's Republic of China, a business operator whose legitimate rights and interests are damaged by unfair competition may file a lawsuit. In practice, there have been civil lawsuits filed on the basis of the above provision.

Law stated - 30 September 2022

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Competent authorities such as the Standing Committee of the National People's Congress, the General Office of the State Council, the National Health Commission and the National Development and Reform Commission, as well as relevant industry associations, have issued regulations and guidelines on anti-corruption and the transparency of medical institutions and medical personnel, which include but are not limited to:

- the Physician Law of the People's Republic of China;
- the Guiding Opinions of the General Office of the State Council on Promoting the Healthy Development of the Pharmaceutical Industry;
- the Opinions on Further Reforming and Improving Policies for Drug Production, Circulation and Use;
- the Guiding Opinions on Strengthening the Prevention and Control of Integrity Risks in Public Medical Institutions;
- the Circular of the General Office of the State Council on the Issuance of Reform Plan for the Management of High-Value Medical Consumables;
- the Circular on the Issuance of Specifications for Centralized Procurement of Drugs by Medical Institutions;
- the Opinions on Further Regulating the Centralized Procurement of Drugs by Medical Institutions;
- the Circular of the Ministry of Health on Further Deepening the Control of Commercial Bribery in the Field of Pharmaceutical Purchase and Sale; and
- the Code of Ethics for Chinese Physicians.

Law stated - 30 September 2022

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PRICING AND REIMBURSEMENT

Price regulation

To what extent is the market price of a medicinal product or medical device governed by law or regulation?

According to the Opinions on Management of Current Drug Price issued by the National Healthcare Security Administration, except for narcotic drugs and first-class psychotropic drugs, which are subject to a government-guided price, all other drugs are priced by the distributors and the prices are market-adjusted. The market prices of drugs, especially commonly used and basic drugs, have fallen sharply because of the two-invoice system and the quantity purchase policy, which generally apply to drug procurement in public hospitals, and profit margins have radically decreased.

Compared with drugs, the prices of medical devices are less affected by policies. However, pursuant to the Guiding Opinions on Promoting the Reform of the Medical Security Fund Supervision System issued by the State Council, the state will improve the market-led price formation mechanism for medical devices. It is generally anticipated that the two-invoice system and quantity purchase policy will also be implemented in the field of medical devices, and the prices of medical devices will be greatly affected by them.

Law stated - 30 September 2022

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

The bidding and procurement process is mandatory for public medical institutions to purchase drugs and medical devices. In this process, price negotiations are generally involved. However, for private hospitals, this process is not applicable.

Law stated - 30 September 2022

Reimbursement

In which circumstances will the national health insurance system reimburse the cost of medicines?

Expenses for drugs can be reimbursed if the drugs purchased are included in the National Drug Catalogue for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, and at the same time the medical institution providing the drugs or prescriptions is eligible for medical insurance coverage. Currently, some regions are piloting the direct reimbursement of retail drugs on a small scale. In addition, the cost of diagnosis and treatment items falling into the Scope of Diagnosis and Treatment Items of National Basic Medical Insurance and the cost of medical service facilities falling into the Scope of Medical Service Facilities of Medical Insurance can also be reimbursed by medical insurance.

Law stated - 30 September 2022

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Price adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

Except for narcotic drugs and first-class psychotropic drugs, the government has abolished the practice of setting drug prices. For the time being, the highest ex-factory prices and the highest retail prices for narcotic drugs and first-class psychotropic drugs are still managed by the National Development and Reform Commission. At present, the prices of medicinal products are set by the market against the background of the two-invoice system and the quantity purchase policy.

The National Healthcare Security Administration and the Ministry of Human Resources and Social Security are the competent authorities for determining the reimbursability of medicinal products.

Law stated - 30 September 2022

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

There is no such statutory obligation.

Law stated - 30 September 2022

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Following the revision of the Drug Administration Law in 2019, the newly amended Measures for the Supervision and Administration of Drug Production and the Measures for the Administration of Drug Registration were released by the State Administration for Market Regulation in 2020. At present, the Regulations for Implementation of the Drug Administration Law, the Measures for the Supervision and Administration of Circulation of Pharmaceuticals, the Measures for the Administration of Drug Distribution Licences and other supporting regulations are being revised.

The aforementioned relevant regulations will further optimise the domestic drug supervision system, stimulate the vitality of domestic drug research and development, strengthen the management of drug intellectual property rights, and promote the optimisation and integration of the domestic pharmaceutical industry and drug research and development as well as the circulation of production resources.

On 9 May 2022, the National Medical Products Administration issued the Regulations for Implementation of the Drug Administration Law of the People's Republic of China (Exposure Draft), which has stipulated targeted measures to encourage the research and development of traditional Chinese medicines, children's medicines and rare disease medicines. In terms of programme setting, the establishment of breakthrough therapy drugs, conditional approval for marketing, priority review and approval and special approval systems will encourage innovation in drug R&D and shorten the process of drug R&D and review. In addition, the stipulation of the market exclusivity period protection for children's medicines and new drugs for rare diseases has been added to the Exposure Draft, which will help encourage enterprises to develop medicines for children and rare diseases.

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