THE HEALTHCARE LAW REVIEW

Fifth Edition

Editor
Sarah Ellson

THE LAWREVIEWS

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PREFACE

Welcome to the fifth edition of *The Healthcare Law Review*. In 2020, we made reference to the covid-19 pandemic and paid tribute to the commitment shown by all working in the sector: the healthcare professionals, the organisational leaders, all staff working in health and social care environments, and the scientists and public health officials seeking to navigate nations through this crisis. Little did we know how this would continue to dominate our lives throughout 2021 and what ingenuity and resilience it would ask of these professionals. This review provides an introduction to healthcare economies and their legal frameworks in 13 jurisdictions, with chapters including Cambodia, Malta and Vietnam. Every country will have been touched by the pandemic and, of course, each has responded in a different way. Some leading healthcare systems have been overwhelmed at times, many have been revealed as vulnerable and limited, and internationally governments and the private sector have shown their ability to innovate, expand capacity and ask more of their systems and professionals than was ever thought possible. The speed with which the vaccines have been developed has defied all previous expectations, and as the world works towards global vaccination we have a new vocabulary and a realisation that we will be expected to live with this new virus.

Our expert authors have reviewed and updated their chapters to reflect the ever-evolving situation in the jurisdictions covered in earlier editions. At the time of writing, many countries were still subject to emergency legislation and altered priorities. The legal position is subject to constant review as countries move through positions in relation to the scale and spread of the coronavirus and the roll-out of vaccination programmes. This review does not seek to navigate the rapidly changing pandemic-based positions, but this year's chapters reveal how underlying systems have changed and may be expected to adapt as a result. As previously, the book reveals both diverse areas of practice and the common challenges and similar approaches in very different countries.

Previous editions considered the rapid expansion of telehealth and telemedicine but few could have foreseen the 3,000 per cent increase in online consultations reported in a number of jurisdictions as we went into lockdown. Regulations, laws and reimbursement had to be revised or rewritten overnight. We will undoubtedly emerge with a newfound confidence about what care can and should be delivered remotely, where the risks that need to be regulated are, and where to prioritise face-to-face interactions between patients and healthcare professionals.

Scopes of practice have been revisited with professionals fulfilling roles outside their usual remit and the recently retired being brought back into practice, often in non-frontline roles, allowing current practitioners to step forward.

Every country wants a health system that cares for the sick and promotes the well-being of its people. Every nation wants to raise the bar to keep up with improving living standards

and expectations. However, every economy requires this to be done at an affordable price. Managing the costs of healthcare and workforce shortages, and ensuring a sustainable model of delivery, have been seen as key drivers in each of the countries covered in this publication. Countries around the world realise that excess deaths and heightened morbidity during the pandemic are not just from coronavirus. Many patients have not attended healthcare facilities for other illnesses or ongoing treatment, and getting care back on track at a time of economic recession with depleted resources and an exhausted workforce will be tough. The virus has asked huge questions of our healthcare systems, and populations will be re-evaluating expectations in the months and years ahead.

Integration between health and wider social care continues to be a key topic, and in countries where care-home mortality has been devastating, further questions are being raised about how social care is expected to operate in conjunction with existing hospital and hospice settings.

This publication identifies the broad characteristics of healthcare to be found in each jurisdiction. It considers: the role of insurance or public payers; models of commissioning; the interplay (or lack of it) between primary, secondary and social care; and the regulatory and licensing arrangements for healthcare providers and professionals.

These have been unprecedented times for the delivery of healthcare and have laid down challenges and opened opportunities. Each chapter describes a country's healthcare ecosystems. I would like to thank the many leading experts for the time and attention they have given to this project, and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson
Fieldfisher LLP
London
August 2021

Chapter 3

CHINA

Min Zhu, Aaron Zhou and Li Zhang[1]

I OVERVIEW

China's healthcare system mainly comprises the healthcare services sector, the healthcare insurance sector, and the drugs and medical equipment sector, which are supervised by three separate government departments. Specifically, the PRC National Health Commission (NHC)[2] is responsible for supervising the medical institutions and medical services industry, the Ministry of Human Resources and Social Security is responsible for formulating the basic healthcare insurance system and policy and for managing healthcare insurance funds, and the National Medical Products Administration (NMPA)[3] is responsible for drug and medical equipment registration and supervision.

II THE HEALTHCARE ECONOMY

i General

Healthcare services can be divided into basic healthcare services and special healthcare services, depending on the scope of coverage and the extent of the specific services.

Basic healthcare services

Basic healthcare services consist of basic public healthcare services and basic medical care services, which the government provides free of charge. The scope of basic public healthcare services in China has been revised and expanded since the launch of China's healthcare reforms in 2009. The National Basic Public Healthcare Service Standard, promulgated in 2017, stipulates that basic public healthcare services consist of 13 types of services, including residents' health file management, vaccinations, healthcare administration for special groups (children aged under six, pregnant women, the elderly, and patients with hypertension, type 2 diabetes, severe mental disorders and tuberculosis), infectious diseases and public healthcare

1 Min Zhu, Aaron Zhou and Li Zhang are partners at Han Kun Law Offices. The firm also wishes to acknowledge the contributions to this publication by Lijuan (Lynn) Wang, counsel at the firm, and Serina Wei, associate at the firm.

2 The duties of the former PRC National Health and Family Planning Commission were merged into the newly established PRC National Health Commission following the implementation of the Programme for the Reform of State Council Organs on 18 March 2018.

3 The NMPA was newly established under the supervision of the State Administration for Market Regulation (SAMR) following the implementation of the Programme for the Reform of State Council Organs.

emergency reporting and treatment. In December 2019, the Law on Promoting Basic Medical and Health Care was promulgated to further the development of medical, hygiene, and healthcare services and ensure citizens' access to basic medical and healthcare services.

Special healthcare services

In addition to basic healthcare services, the Chinese healthcare system also includes special healthcare services. Special healthcare services refer to medical services provided by medical institutions to satisfy special medical needs, such as special surgical operations, full nursing care, special wards, specialist outpatient services and medical cosmetic surgery.

ii The role of basic medical insurance

China's basic medical insurance system currently consists of basic urban employee medical insurance and basic medical insurance for urban and rural residents. Basic urban employee medical insurance is compulsory for all urban employers and employees. Meanwhile, all urban and rural residents who are not covered by basic urban employee medical insurance may choose to purchase basic medical insurance for urban and rural residents, including personnel under the flexible working hour system who have difficulty participating in basic urban employee medical insurance. By the end of 2020, the number of people participating in the two basic medical insurance schemes reached 1.36 billion, with the coverage stabilising at over 95 per cent of the population of China.[4]

iii Funding and payment for special healthcare services

In addition to basic healthcare services, both public and non-public medical institutions also provide special healthcare services to satisfy non-basic medical needs. However, the amount of special healthcare services provided by a public medical institution cannot exceed 10 per cent of all healthcare services it provides.

Under the current basic medical insurance system in China, the national medical insurance system does not cover the cost of special healthcare services. Such costs are to be directly undertaken by the individuals incurring the costs or reimbursed under commercial health insurance.[5]

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i China's healthcare service system

China's healthcare service system is developed under a dual structure for urban and rural areas. The rural healthcare system is composed of three levels of medical institutions, which are county hospitals, township hospitals and village clinics. The urban healthcare system is also made up of three levels of medical institutions, which are regional central hospitals,

4 See 'Statistical Bulletin on the Development of Medical Security Undertakings in 2020' published by the National Healthcare Security Administration on 8 March 2021.

5 Opinions of the CPC Central Committee and the State Council on Deepening Reform of the Medical and Healthcare Systems, Article 10 (promulgated by the CPC Central Committee and the State Council on 17 March 2009).

community healthcare service centres, as well as clinics and infirmaries. Densely populated cities also have tertiary hospitals with more advanced technologies and equipment. The entire healthcare service system is known as the 'dual and three grades' system.

ii Graded treatment system

In China, patients can freely choose hospitals to receive medical treatment. However, public hospitals have often been overcrowded because they possess better medical resources.[6] By contrast, community hospitals are less frequently visited, although they provide more accessible and convenient healthcare services to residents. In response to this issue, the Guiding Opinions on Promoting Graded Medical Treatment System Construction was promulgated in 2015 to alleviate overcrowding and promote the rational allocation of medical resources. The guiding opinions describe the establishment of a graded medical treatment system including initial diagnoses at community medical institutions, two-way referrals, divisions for acute and chronic diseases, and communications between institutions. At present, China is promoting the implementation of such graded medical treatment system by building medical consortiums.[7]

Meanwhile, China is actively establishing and improving the healthcare services system for the elderly: community healthcare service centres provide continuous health management and medical care; general medical institutions are convenient for the elderly to make appointments with doctors; in addition, elderly care institutions that meet certain conditions may establish geriatric disease hospitals, rehabilitation centres and nursing homes that, if qualified, may be designated as being within the scope of basic healthcare insurance for urban and rural residents.[8] Additionally, China supports pension institutions to establish medical institutions and medical institutions to establish pension institutions.[9]

iii Application of electronic medical records

Electronic medical records are an important means to promote healthcare services informatisation and will help to improve the quality and efficiency of medical services. In 2010, the Ministry of Health, a predecessor to the NHC, initiated work on its hospital informatisation construction pilot scheme, focusing on the promotion of electronic medical records.[10] Since then, the use of electronic medical records has become more popular across the country. In 2017, the National Health and Family Planning Commission, also a predecessor to the NHC, promulgated the Regulations on the Management of Electronic Medical Records Applications (for Trial Implementation), which stipulate a series of

6 China Health Industry Bluebook (2017), page 16 (China National Pharmaceutical Industry Information Center, 2017).

7 Guiding Opinions on Promoting the Building and Development of Medical Consortiums (promulgated by the General Office of the State Council on 23 April 2017).

8 See Circular of the General Office of the State Council on Transmitting and Issuing the Guiding Opinions of the Health and Family Planning Commission and Other Departments on Promoting Integration of Medical and Elderly Care Services (No. 84, 2015).

9 Circular on Completing the Examination and Approval of Medical and Pension Institutions (promulgated jointly by the NHC, the Ministry of Civil Affairs, the SAMR and the National Administration of Traditional Chinese Medicine on 27 May 2019).

10 Circular of the Ministry of Health on Launching Electronic Medical Records Pilot Reform and Working Plan for Electronic Medical Records Pilot Reform (promulgated by the Ministry of Health on 28 September 2010).

requirements for the content, writing and saving, use and storage of electronic medical records. The regulations, together with a series of supporting national and industry standards for electronic medical record systems, data management and medical terminology, constitute the framework for the management of electronic medical records in China. At present, the NHC continues to promote the nationwide digitisation of medical records in medical institutions, such as by evaluating the levels of electronic medical records management at different medical institutions.

iv Personal information protection

China has gradually established and improved its personal information protection system through the promulgation of legislation, judicial interpretations, rules and voluntary national standards, including the Data Security Law, the Cybersecurity Law, the Interpretation of Several Issues concerning the Application of Law in the Handling of Criminal Cases of Infringement of Citizens' Personal Information, the Measures for Determining the Illegal Collection and Use of Personal Information by Apps, and the Information Security Technology – Personal Information Security Specification (GB/T 35273-2020). The PRC Civil Code, which came into force in January 2021, has a specific chapter that provides for the protection of personal information, laying the foundation for the enactment of laws such as the Personal Information Protection Law.

Meanwhile, special attention has been paid to the healthcare sector with respect to personal information protection. The Provisions on Administration of Medical Records in Medical Institutions, promulgated in 2013, require medical institutions and their medical staff to keep strictly confidential personal information contained in patients' medical records and not to disclose personal information for non-medical, teaching or research purposes. The Measures for Administration of National Health and Medical Big Data Standards, Security and Services (for Trial Implementation), promulgated in July 2018, require local storage of health and medical big data. Furthermore, in accordance with the Regulations on Administration of Human Genetic Resources, if the relevant personal information is classified as human genetic resources information, any collection, preservation, utilisation and disclosure thereof shall comply with certain requirements, including ethical reviews, prohibition on purchase and sale, prohibition on collection or preservation by foreign or foreign-controlled organisations, individuals or institutions, and prohibition of cross-border transfers. Additionally, the Information Security Technology – Personal Information Security Specification, a voluntary national standard revised in October 2020, lists personal medical treatment records as personal sensitive information, and recommends additional measures to be taken for the transfer, storage, access control, processing, sharing and transfer of personal sensitive information. The Information Security Technology – Guide for Health Data Security, a voluntary national standard that came into effect in July 2021, provides further guidance for the use and protection of personal health and medical information.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The NHC is the government authority primarily responsible for approving the establishment of medical institutions in China, and for practice approval and administrative oversight. Specifically, the NHC is responsible for:

a developing medical institutions, medical technology applications, medical quality, medical safety and medical service policy and organisational standards;
b developing medical personnel practice and service standards;
c formulating medical institution and healthcare industry administrative measures and exercising supervision;
d participating in drug and medical equipment clinical trial administration; and
e leading the oversight of nationwide medical institution assessments, and developing public hospital operating oversight as well as performance evaluations and assessments.

ii Institutional healthcare providers

Establishment of medical institutions

Medical service providers that intend to set up medical institutions and practise medicine in China must comply with the local Medical Institutions Establishment Plan and obtain approval from the NHC. Before a medical institution commences operations, it shall obtain approvals from the NHC in two steps: the establishment approval and the approval to practise medicine. When preparing to establish a medical institution, the medical institution operator shall submit a detailed report to the NHC to describe the establishment preparation plans, including site selection, diagnosis and treatment projects, institution size (number of ward beds), funding sources and planning, personnel status and management systems. Construction of a medical institution may commence after the NHC approves its establishment. After completing the necessary preparatory work, such as site construction, equipment purchases, personnel hiring and system construction, the medical institutions shall apply to the NHC for a permit to practise medicine.

Penalties for violations by medical institutions

When practising medicine, medical institutions must strictly comply with the approved business scope and approved medical treatment projects, the relevant laws and regulations and technical standards. Medical institutions that operate without a permit, or whose medical treatment activities exceed the scope specified therein, may be fined, have their illegal income, drugs and equipment confiscated or their practice permits revoked.

New regulations for doctors establishing personal clinics

Several recent regulatory developments have broadened the eligibility of those who may establish personal clinics in China. In February 2017, revisions to the Rules for Implementation of the Regulations on Administration of Medical Institutions allow individuals who currently serve in medical institutions, are retired due to illness or have been suspended from duty without pay to apply to establish medical institutions. In April 2019, the NHC, together with four other government authorities, jointly issued the Circular on Printing and Issuing the Opinions on the Pilot Programme for the Promotion and Development of Clinics, which encourages doctors who have practised for at least five years with intermediate or higher qualifications to establish specialist clinics on a full- or part-time basis. This is regarded as a major step in China's reforms to permit doctors to freely practise medicine and establish personal clinics.

iii Healthcare professionals

In China, physicians, nurses and pharmacists must practise medicine in accordance with the Law on Licensed Doctors, the Regulations on Nurses and the Regulations on Administration of Medical Institutions as well as other relevant administrative requirements.

Medical practice by medical practitioners

Medical practitioners are subject to a registration system. Candidates who possess the requisite degree, have work experience as assistant physicians or have practised medicine after engaging in clinical practice for a certain period under the guidance of a practising physician may sit for the medical practitioner licensing examination. After passing the examination, candidates may obtain a medical practitioner's licence and register to practise medicine with the healthcare administrative authority.

The registration of medical practitioners will remain valid indefinitely. However, registered medical practitioners are subject to regular assessments of their professional abilities, work performance and professional ethics by an NHC-designated agency. Practitioners who fail an assessment will be ordered to suspend their practice for three to six months to attend training and continuing medical education.

Anyone who practises medicine without registration will be ordered to cease practising, be fined or have his or her illegal income, drugs or equipment confiscated. If an unregistered practitioner causes any serious consequences, such as injury to patients or spreading or potentially spreading diseases, the wrongdoer may be subject to criminal liability under Article 336 of the Criminal Law, which stipulates liabilities for illegally practising medicine.

Foreigners wishing to practise medicine in China (e.g., foreign-registered physicians) need to first obtain an invitation or employment from a Chinese hospital before applying for a Temporary Licence for Foreign Physicians to Practise Medicine in China, which allows foreign physicians to perform clinical diagnosis and patient treatment in China for no more than one year. Foreigners who intend to become long-term physicians in China must pass the national medical practitioners licensing examination and obtain a practice certificate before registering as medical practitioners in China.

Practice by nurses

Candidates intending to practise nursing also need to pass a qualification examination and complete the registration process. Prior to the registration, candidates need to complete the prescribed professional nursing courses and engage in clinical nursing practice for a certain period. Registered nurses shall practise nursing at their registered practice locations. Nursing practice registrations are valid for five years. Upon expiry of the registration term, registered nurses may apply to the health administrative authority to renew their registrations.

Multi-site practice

The previous Interim Measures for Registration of Medical Practitioners stipulated that physicians were only permitted to practise medicine at the medical institution registered as their place of practice, which effectively meant that physicians could only practise medicine at one medical institution. Since the promulgation of the final Measures for Administration of Registration of Medical Practitioners in 2017, doctors have been able to practise medicine at multiple medical institutions in multiple locations, including internet hospitals.

V NEGLIGENCE LIABILITY

Medical institutions and physicians that cause harmful injuries to patients during the provision of medical services may be held liable in accordance with the relevant provisions on liability for medical malpractice in Chapter 6 of Part VII of the PRC Civil Code. The medical institution shall be liable if the medical institution or its medical workers are at fault and, in certain circumstances, presumed to be at fault. In addition, the Regulations on Handling Medical Accidents also specify rules related to the prevention, handling, technical evaluation and administration of medical malpractice cases. Furthermore, when a physical injury occurs, if the relevant liability is not provided for in the PRC Civil Code or the Regulations on Handling Medical Accidents, the relevant provisions of the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in Hearing Personal Injury Compensation Cases may apply.

i Overview

When hearing a medical dispute, courts often assess the liability of the medical institutions from three aspects: first, whether the medical institution is at fault and the extent of the medical institution's involvement in the malpractice; second, the cause and effect between the fault of the medical institution and the damage or injury suffered by the patient; and third, the extent of loss and injury suffered by the patient. In general, a medical malpractice determination is regarded as a neutral and credible basis to determine the allocation of fault between medical institutions and patients. Unless the procedure for making the medical malpractice determination was not lawful, courts tend to depend upon such determination to allocate fault and decide the liabilities of the medical institution.

ii Notable cases

The dispute over medical malpractice between Shen Bo, Meng Xiaoxia and the Second Affiliated Hospital of Zhengzhou University in 2014[11] is of notable significance as the relevant medical institution was presumed to be at fault. In this case, the plaintiff's position was that the defendant hospital should bear full responsibility for the death of the patient because the hospital had committed serious malpractice in treating the patient and had tampered with medical records for the purpose of avoiding responsibility. However, the defendant argued that the hospital revised the medical records solely for the purpose of improving the content of the records and that there was no substantial difference between the original records and the modified records. The court did not find the defendant's argument reasonable. Both the first and second instance courts held that the hospital was presumed to be at fault and therefore should be primarily liable for the malpractice claim, as it had tampered with and concealed medical records and failed to give a reasonable explanation for that conduct.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

The basic healthcare system is the cornerstone of China's medical and healthcare system, whereby public medical institutions are obliged to provide the substantial part of basic healthcare services. Public medical institutions include government-funded medical

11 Ref doc No.: (2014) Zheng Min Yi Zhong Zi No. 500.

institutions and medical institutions run by state-owned enterprises. For historical reasons, public medical institutions have easier access to high-quality medical resources, including scientific research and teaching, clinical trials, advanced equipment and professionals.

In recent years, China has encouraged private capital to invest in medical institutions so that private medical institutions may participate in the provision of medical services. However, although the number of private medical institutions as of March 2021 was twice that of public medical institutions,[12] public health institutions still dominate the medical services market because of the high-quality medical resources that they possess. Statistics published by the NHC show that there were nearly 800 million visits to public hospitals in the first quarter of 2021, 5.7 times the number to private hospitals.[13]

Medical institutions can also be categorised into non-profit and for-profit medical institutions according to their operating objectives. Non-profit medical institutions primarily serve the public interest and generate revenues to cover the cost of healthcare services, with all profits being used to upgrade the institution, such as improving medical treatment conditions, importing technologies, and developing new healthcare service programmes. On the other hand, for-profit medical institutions provide economic returns to investors. Public medical institutions and government-funded medical institutions are generally non-profit, while private medical institutions can choose to be non-profit or for-profit. The Chinese government manages non-profit and for-profit medical institutions according to their categorisation and tends to support non-profit medical institutions through taxation, pricing and other policies.[14]

Foreign-invested medical institutions wishing to enter the Chinese market shall refer to the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020) (the Negative List), which restricts foreign investment in medical institutions to the form of a Sino-foreign equity joint venture. Foreign capital or equity is generally not allowed to exceed 70 per cent in foreign-invested medical institutions. However, service providers from Hong Kong, Macao and Taiwan are permitted to establish wholly owned hospitals in some provinces and municipalities in mainland China. The Interim Measures for Administration of Sino-Foreign Joint Venture and Contractual Joint Venture Medical Institutions further stipulate the total investment amount, the minimum percentage of Chinese capital or equity and the term of operations of Sino-foreign joint venture medical institutions. In addition, the local Medical Institution Organisation Plan shall also be complied with when establishing foreign-invested medical institutions.

12 According to statistics published by the NHC on 24 May 2021.

13 According to statistics published by the NHC on 24 May 2021

14 Non-profit medical institutions established by the government may enjoy financial subsidies from the government. Other non-profit and for-profit medical institutions do not enjoy such subsidies. Non-profit medical institutions price their healthcare services according to the direction of the government and enjoy corresponding preferential tax treatments. For-profit medical institutions enjoy the freedom to set the prices, run their operations independently and pay taxes according to the relevant laws and regulations. See Proposals for the Categorised Management of Medical Institutions in Urban and Rural Areas, No. 233, 2000.

VII COMMISSIONING AND PROCUREMENT

China is committed to optimising the price of medical services and drugs. Since the latter half of 2018, China has begun to carry out a pilot 'centralised procurement policy' for certain drugs in 11 cities, centralising the procurement of drugs by public medical institutions across regions. Procurement is made in large quantities to encourage pharmaceutical companies to reduce drug prices and to relieve the cost burden on patients.[15] Given the positive effect of the pilot policy, in 2021 China has continued its nationwide expansion of the centralised medical procurement policy.[16]

VIII MARKETING AND PROMOTION OF SERVICES

In China, advertisement of medicines, pharmaceuticals, medical equipment and food is subject to content reviews by the advertising authorities.[17] Advertisement review authorities include the NMPA, the NHC and the SAMR.

Under the Advertising Law (revised in 2021), drug and medical device advertisements cannot include:

a assertions or guarantees as to efficacy and safety;
b efficacy rates or cure rates;
c comparisons of the safety or efficacy of drugs or medical devices with those of other medical institutions;
d the use of spokespersons to endorse or provide testimonials; and
e medical advertisement disguised as health and well-being advice.

According to the Law Against Unfair Competition (revised in 2019), discounts, profit sharing, and similar inducements directly given to transaction counterparties to promote the sale of drugs and medical equipment are not considered to undermine the interests of third parties or consumers and are generally regarded as lawful market behaviour rather than bribery.[18] When a party to a transaction intends to give such inducements to a counterparty or pay a commission to middlemen, such party shall express its intentions clearly and enter these items truthfully in its accounting records.

15 See the Circular of the General Office of the State Council on Printing and Issuing the Plan for the Government's Pilot Organisation of the Centralised Procurement and Use of Medicine (promulgated by the General Office of the State Council on 1 January 2019).

16 Opinions of the General Office of the State Council on Promoting the Normalisation and Institutionalisation of the Centralised Drug Volume Procurement (promulgated by the General Office of the State Council on 22 January 2021).

17 PRC Advertising Law, Article 46 (amended by the Standing Committee of the National People's Congress on 29 April 2021).

18 Note: if the transaction parties involve state-owned entities (e.g., public hospitals), such profit sharing may jeopardise the value of state-owned assets. Therefore, under the framework of the Criminal Law, if a transaction party gives a benefit to another party that is a state-owned enterprise, public hospital or other state-owned entity, it may be deemed as bribing a state entity. Acceptance of such benefits by a state-owned enterprise or public hospital may constitute the crime of accepting a bribe by a state entity.

IX CORONAVIRUS

Since the outbreak of the covid-19 pandemic in January 2020, China has conditionally approved multiple applications for registration of covid-19 vaccines pursuant to the PRC Vaccine Administration Law and the PRC Drug Administration Law. Meanwhile, the NMPA has also promptly initiated the emergency approval mechanism for medical devices and quickly approved a batch of urgently needed medical devices, especially in vitro diagnostic reagents. China successfully controlled the pandemic in a timely and efficient manner thanks to this quick response mechanism, among other control measures.

The Regulations on the Supervision and Administration of Medical Devices (revised in 2021) summarise the experience of epidemic prevention and control and introduce and improve the following systems to respond to major public health emergencies: first, a priority review and approval system, which gives priority to the review and approval of innovative medical devices; second, a conditional approval system, which allows conditional approvals for urgently needed medical devices in response to public health events based on a comprehensive balancing of risks and benefits; third, an emergency use system that permits medical devices to be used within a certain scope and a certain period of time in case of any major public health emergency or other emergencies that seriously threaten public health.[19]

X FUTURE OUTLOOK AND NEW OPPORTUNITIES

'Internet plus' and medical big data are currently two popular concepts in China. Many start-ups and investment institutions are especially focused on emerging businesses including telemedicine, internet hospitals, mobile medicine, smart medicine and other medical service sub-sectors.

These emerging forms of healthcare have played a significant role in promoting the diversification of medical services as advocated by the state. Regulators have become more open to the application of the internet and big data technology in medical services. In April 2018, the State Council promulgated Opinions on Promoting the Development of 'Internet plus Healthcare', promoting a comprehensive online healthcare service system, encouraging medical institutions to use the internet and other information technologies in developing the scope and contents of healthcare services, allowing medical institutions to develop 'internet hospitals' that provide online diagnosis of common diseases and follow-up consultations for chronic diseases, supporting medical institutions to cooperate with third-party organisations to establish online platforms for long-distance healthcare consultations, health management and other services, and promoting the exchange of medical resources and information.

In September 2018, the NHC and the State Administration of Traditional Chinese Medicine jointly promulgated three documents concerning 'Internet plus Healthcare', namely Measures for the Administration of Online Medical Diagnosis (for Trial Implementation), Measures for the Administration of Online Hospitals (for Trial Implementation), and Good Practices for Telemedicine Services (for Trial Implementation), which means the industry-focused 'Internet Medical Policy' has finally been implemented. However, as a new medical service model, these new measures remain conservative on online medical services from the following perspectives:

19 See replies of the NMPA officials to journalists regarding the Regulations on the Supervision and Administration of Medical Devices on 26 March 2021.

a internet hospitals and internet-based diagnosis services must rely on bricks-and-mortar medical institutions, and be subject to market access administration and governmental approval;

b a unified provincial-level supervision platform has to be established to ensure medical quality and safety of the new online medical services (also, all medical institutions that carry out internet-based diagnosis activities are required to keep records during the whole process and provide relevant authorities with access to such records);

c internet-based diagnosis services are restricted to subsequent consultations for certain common diseases, chronic diseases and Internet-plus family doctor signing services. No internet-based diagnosis services may be provided to patients seeking initial medical consultations; and

d telemedicine services may only be carried out between bricks-and-mortar medical institutions.

Furthermore, with respect to the fast-developing field of gene detection and diagnosis, the Negative List provides that the 'development and application of human stem cells, gene diagnosis and treatment technology' is still a prohibited industry for foreign investment, and therefore foreign capital still cannot participate in gene detection and diagnosis projects in China.

XI CONCLUSIONS

China has launched a new round of healthcare reforms since 2009. At present, this round of reforms is ongoing and faces challenges such as improving the graded healthcare system, implementing electronic medical records, relaxing restrictions on doctors to practise medicine, promoting the centralised procurement policy, continuing to promote payment method reforms for basic medical insurance and achieving the optimal allocation of medical resources. Nevertheless, as China is navigating these challenges, the reforms also present an unprecedented opportunity for private-sector investors to participate in the medical and healthcare industry.

Appendix 1

ABOUT THE AUTHORS

MIN ZHU

Han Kun Law Offices

Mr Zhu has extensive legal practice experience in the life sciences and healthcare industries. He has served life sciences and healthcare companies in different stages of development, including financing and licensing deals for start-ups, mergers and acquisitions, and various regulatory and compliance matters, such as anti-corruption and anti-bribery, clinical trials, drug and medical device registration, distribution, advertising and promotion, as well as medical and healthcare data compliance. Prior to joining Han Kun, Mr Zhu practised law for many years at another leading Chinese firm and also in the Shanghai office of an international law firm. Mr Zhu has been consistently recognised as a highly recommended practitioner in life sciences, healthcare, and corporate compliance by leading global legal ranking organisations such as *Chambers and Partners* and *The Legal 500*.

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Mr Zhou's practice focuses on cross-border and domestic mergers and acquisitions, private equity investment, venture capital investment, foreign direct investment, joint ventures and technology/IP licensing. Mr Zhou's extensive experiences in the pharmaceutical and healthcare field include out-licence/in-licence and supply agreements for the development and commercialisation of new drugs and generic drugs, sale and purchase of pharmaceutical-related assets and businesses, investments in and acquisitions of pharmaceutical and healthcare companies, research collaboration and manufacturing services agreements, and FCPA-related and compliance matters. Mr Zhou has over 16 years' legal experience, including five years at Davis Polk and three years as the Asia Pacific legal head of a Fortune Global 50 company. Mr Zhou is a member of the PRC Bar and of the New York State Bar.

LI ZHANG

Han Kun Law Offices

Ms Zhang specialises in private equity and venture capital investment, mergers and acquisitions, reorganisations, restructurings, public listings, foreign direct investment and general corporate matters. She has provided legal services to numerous private equity investors, venture capital and start-up or innovation companies, handling legal matters in transaction structures, transaction terms, transaction closings and dealing with other comprehensive transaction issues from both legal and business perspectives. Ms Zhang represents clients who cover a wide variety of new economy industry sectors, including life sciences and healthcare, innovation technology and manufacturing, new energy, environmental protection, cross-border commerce, mobile internet and education.

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