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# Digital Healthcare 2022

China: Trends & Developments

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# Trends and Developments

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## Overview

Digital healthcare is not yet a clearly defined term under the current People's Republic of China (PRC) legislative framework. In practice, digital healthcare in China is generally referred to as "the application of digital technologies in the medical and health sectors", which mainly includes internet hospitals, online sale of drugs, AI-based medical devices, big data and medical robots, among others. The rapid growth of emerging technologies and the continuous support from the Chinese government has caused a digital transformation and the acceleration of China's healthcare sector in recent years. This in turn improves the quality and efficiency of healthcare services and hospital management.

The outbreak of the COVID-19 pandemic in early 2020 drove wider acceptance of telemedicine and forced online platforms to provide a full range of services covering online diagnosis and treatment, drug sale and deliver and online payment as well as medical insurance reimbursement services.

By the end of 2021, the number of internet hospitals in China exceeded 1,900, representing a rise of 400% compared with 2019. The market size of internet hospitals and online sales of drugs has reached around RMB223 billion and RMB36.8 billion respectively, representing an increase of approximately 44% and 52% respectively, on a year-on-year basis. However, offline hospitals have played a key role during the COVID-19 pandemic as the scope of online medical services and dispensing of prescription drugs available online is still quite limited.

China's digital healthcare sector experienced a boom in 2021 in terms of investment, financing and market size. The market size of China's digital healthcare reached approximately RMB410 billion in 2021, a 41% increase on a year-on-year basis. The total financing in the digital healthcare industry hit a record RMB18 billion, an approximately 40% increase on a year-on-year basis, while the total number of financing transactions increased by around 70%.

In 2021, the Chinese government continued its efforts to further open up the digital healthcare sector to foreign investors. Following the release of local policies to encourage eligible foreign investments in "Internet plus Healthcare" by the Beijing Municipal Commerce Bureau in December 2021, the State Council released the Revisions to Administrative Provisions on Foreign-Invested Telecommunications Enterprises in April 2022. This regulation is expected to further facilitate foreign investment in the digital healthcare sector by substantially relaxing qualification requirements for such investors in online healthcare platforms that hold the Value-added Telecommunication Business Licence.

However, with respect to business involving collection, storage, provision or otherwise processing of personal information, human genetic resources, sensitive healthcare information, or information having national security concerns, the Chinese government has tightened its regulations on foreign participation.

## New Technologies and Applications

With the advances in digital technologies such as the internet, AI, robotics, 5G, blockchain, big data and 3D printing, China's healthcare sector

is entering an era of full digitalisation by applying the new technologies in various healthcare service scenarios, including disease prevention, diagnosis, surgery, hospital management, health management, healthcare data analysis and processing. The following are the main applications of the new technologies in China's healthcare sector.

### *Telemedicine or online healthcare*

Telemedicine has become one of the most popular and fast developing areas of China's digital healthcare industry, as a result of the innovative applications of internet technology and the implementation of national polices promoting "Internet plus Healthcare".

From the regulatory perspective, telemedicine services can be generally divided into the following two categories.

- Online diagnosis and treatment service – which under applicable laws and regulations are basically limited to online diagnosis, treatment and prescription services for subsequent visits of outpatients with certain common and chronic diseases. Providers of internet-based diagnosis and treatment services are required to be licensed medical institutions (also known as internet hospitals) in addition to meeting the qualifications necessary for the operation of internet platforms.
- Non-diagnosis healthcare services – which mainly include non-diagnosis medical and health consultation, online hospital appointment registration, drug sales and delivery. Operators providing these online services do not have to be licensed medical institutions, while other qualifications for the operation of internet platforms may still be required.

The establishment and operating models of internet hospitals are becoming more diverse. In the early stages, internet hospitals were mainly sponsored by large internet providers together with certain private hospitals. Driven by the COVID-19 pandemic, many public hospitals launched their own internet hospitals to extend their medical services. Other players in the healthcare system, such as insurance companies and pharmaceutical companies, have also participated in the investment and operation of internet hospitals. Meanwhile, the acceleration of reimbursement of internet medical costs by China's medical insurance fund since 2021 has further boosted the internet healthcare industry.

However, despite that large internet healthcare platforms saw a significant rise in their revenues in 2021 (especially revenue from the online sale of drugs), their profitability still remains relatively low compared to offline services as the unit price of online services and consumers' willingness to pay for them are still relatively low.

### *AI-based applications*

AI technology is one of the core technologies fuelling the expansion of the digital healthcare market and is being used in a number of areas including, disease prediction, clinical decision support systems, drug development and auxiliary diagnosis, with a prominent area being imaging auxiliary diagnosis.

Whether an AI-based medical software or system should be regulated as a medical device under PRC laws mainly depends on its intended functions and usages (see **Major Regulatory Developments in Digital Healthcare Sector – AI-based medical devices** for more details). It is worth noting that, since the National Medical Products Administration (NMPA) approved the first Class III AI-based medical device in early 2020, the commercialisation and approval process of these devices has gradually accelerated. By the end of 2021, over 20 types of AI medical software have been granted Class III medical device licences, most of which are

medical imaging AI products. This has enhanced the investment and financing in the AI medical imaging industry. It is reported that a dozen Chinese AI medical imaging companies have been pursuing an IPO since 2021.

### *Medical robots*

The Chinese government introduced policies to promote the use of medical robots in 2012. Their use has been growing rapidly since 2019 and they have been applied in various healthcare scenarios (eg, medical guidance, surgery, rehabilitation and nursing) to produce efficiency and accuracy in healthcare services. However, China's medical robot market is still in its early stage compared to the United States and Europe, mainly due to its high cost and safety concerns. In February 2021, China's Ministry of Industry and Information Technology released the Draft Medical Equipment Industry Development Plan (2021–2025) for public comments, to encourage the development of surgical robots. In addition, the National Healthcare Security Administrations (NHSA) and its local counterparts in certain provinces, such as Shanghai and Beijing, also issued relevant policies to cover the costs of surgical robots through local medical insurance funds. These policies are expected to accelerate development of the Chinese medical robot market.

### *5G teleconsultation*

5G technology plays a crucial role in the digital transformation of hospitals, especially in the area of remote teleconsultation, by allowing access to patients' records in seconds, sharing medical images and obtaining virtual guidance from experts in different fields in real time. It is expected that 5G network coverage will become one of the main goals for hospital infrastructure upgrade. For example, Shanghai has issued a policy for the implementation of 100% 5G coverage in all class A tertiary hospitals by 2023. 5G is expected to be applied in medical scenarios in more innovative ways.

### *Healthcare data and blockchain*

Healthcare data mainly refers to data generated in the process of disease prevention, medical treatment and health management. The tamper-proof feature of blockchain technology could help to build up a system featuring credible storage, compliant sharing and whole-process traceability of healthcare data. In recent years, the National Health Commission (NHC) and its local counterparts have been making efforts to set up a nation-wide healthcare data infrastructure (eg, an all-citizen health information platform) by using big data and blockchain technologies with the intention to facilitate interconnectivity and information sharing between hospitals. Moreover, during the COVID-19 outbreak, information technologies such as big data have been widely used for prevention, control and management of the pandemic. In particular, the application of a "health code" by recording key personal data such as personal health status, vaccination information, COVID PCR testing results, travel and other traceable information has been very helpful in China's successful control of COVID-19 in the past couple of years.

### *3D printing*

As an important and frontier area in the application of 3D printing technology (also known as additive manufacturing technology), medical 3D printing has been used by hospitals in China mainly in pre-operative planning, surgical guides and patient-tailored implants. Though medical 3D printing has significantly improved the personalisation and accuracy of medical services, currently its application in China is relatively limited and mainly focuses on external medical devices for dental and orthopaedic applications. The Draft Medical Equipment Industry Development Plan (2021–2025) (see **New Technologies and Innovation – Medical Robots**) proposed the development of new products in the field of "3D printing plus medical health" and promotion of customised medical services and devices

such as rehabilitation equipment, implants and soft tissue repairing treatment. Some provincial governments have gone further to set up pricing guidance and policies for medical 3D printing devices in an effort to make sure costs related to medical 3D printing are covered by local medical insurance and are more affordable for patients.

## Major Regulatory Developments in the Digital Healthcare Sector

The legislative and regulatory developments in China's digital healthcare sector since 2021 mainly focused on the following areas.

### *Telemedicine and online healthcare*

China launched three regulations in 2018 (the Administrative Measures for internet-based Diagnosis and Treatment, the Administrative Measures for Internet Hospitals and the Good Practices for Telemedicine Services – all for Trial Implementation) to provide a general legal basis for the administration of telemedicine and other online healthcare services. With the rapid development of China's internet healthcare industry, a variety of non-compliant practices and malpractice phenomena in Chinese internet healthcare industry also sprang up, including:

- online malpractice by disqualified physicians;
- online diagnosis by AI rather than qualified physicians;
- lack of standard operating procedures and guidelines for online diagnosis and treatment;
- prescription of drugs which could not be prescribed online; and
- operation of online diagnosis and treatment platforms by unqualified operators.

With an aim to address these issues, the NHC released the Detailed Rules for Regulation of Internet-based Diagnosis and Treatment (Draft for Comments) in October 2021, putting forward detailed requirements for operators of internet diagnosis and treatment platforms, their personnel, business scope, service quality and safety, among others.

To reinforce the supervision on safety and quality of online medical services, the rules specified that, to the greatest possible extent, the internet-based diagnosis and treatment services provided should be of the same quality as those provided by medical institutions offline. The rules also specified that the platforms of medical institutions providing online diagnosis and treatment services should be connected to a supervision platform established by provincial authorities and ensure the traceability of the entire online medical service.

Furthermore, although the NHSA issued a series of policies during 2019–2020 to propose "equal treatment for online and offline services" in terms of medical insurance reimbursement, the implementation of these policies at the provincial level remains a challenge. To push its local counterparts to improve payment agreements signed by local medical insurance institutions for funding "Internet plus Healthcare" services and to accelerate the implementation of an electronic supervision system to strengthen the management of medical insurance funds, NHSA issued the Opinions on Optimising Convenient Services in Health Insurance in July 2021.

Furthermore, in February 2022, NHC announced that it would make efforts to optimise the pricing management of "Internet plus Healthcare" services and policies via payment by the medical insurance fund. Currently, most governments at the provincial level have issued local pricing policies and guidance for "Internet plus Healthcare" services. It is believed that these regulatory efforts and favourable policies will facilitate the rapid advancement of China's internet healthcare industry.

### *AI-based medical devices*

In 2017, the NMPA updated the Catalogue of Medical Device Classification to formally classify AI-based medical software (including analysis and processing software for medical imaging and pathology images) as Class II or Class III medical devices for the first time

With the ever-changing development and innovative adoption of AI technologies in medical software, it is still difficult to determine if a novel application of AI medical software should be regulated as a medical device and which category of medical device it falls into, according to the classification criteria under the existing rules. This has brought compliance uncertainties and confusion to many developers and manufacturers of AI-based medical devices.

In order to establish a clearer regulatory direction for medical AI application, the NMPA issued the Guidelines for Classification and Definition of Artificial Intelligence Medical Software Products in July 2021, which defined AI medical software as AI-powered software to be used for medical purposes by processing data from medical devices. The Guidelines also elaborated key factors to consider when determining the classification of AI medical devices, including the intended use of the product (eg, whether it is for supporting physician's decision-making) and its algorithm maturity. In March 2022, the NMPA further released three guidelines:

- the Registration and Review Guidelines for Artificial Intelligence Medical Devices;
- the Registration and Review Guidelines for Medical Device Software; and
- the Registration and Review Guidelines for Medical Device Cybersecurity.

These were aimed at further streamlining and optimising China's review and approval system for AI-based medical devices.

### *Healthcare data protection*

In the absence of unified and specific legislation on data protection in the healthcare sector in China, regulatory requirements on healthcare data protection are scattered in various general laws and regulations, as well as in national standards and industry guidance. A series of new regulations and policies have been announced by the Chinese government since 2021, in an effort to strengthen data protection and online security in the healthcare sector, which include the following.

- The Personal Information Protection Law issued in August 2021 classifies personal information on medical health as "sensitive personal information" which should be afforded a higher level of protection than ordinary personal information.
- The Draft Network Data Protection Regulations, issued in November 2021 for public comments, proposed to establish a data classification and graded protection scheme, by classifying data as "important data", "core data", and "general data" and granting corresponding protection measures for different categories of data. It is noteworthy that genetic and other healthcare data that meet the scale or accuracy required by relevant authorities are classified as "important data" (detailed catalogues of "important data" are yet to be formulated) and thus will be subject to special protection requirements for "important data". Healthcare data processors who handle more than one million pieces of personal information are also subject to special requirements for "important data" and may be required to go through a cybersecurity review when seeking for listing abroad. Furthermore, Critical Information Infrastructure Operators in the healthcare industry (the guidance on identifying such operators remains to be further clarified) and cross-border transfer of healthcare data involving personal informa-

tion will be subject to additional and stricter data protection requirements and government registration, filing or approval procedures.

- The Detailed Rules for Regulation of Internet-based Diagnosis and Treatment (Draft for Comments) required that platforms providing online diagnosis and treatment services should go through registration or filing procedures applicable for the third level of information security protection system. They should also establish internal mechanism and enter agreements with relevant partners in relation to cybersecurity, personal information protection and data use management.
- The Registration and Review Guidelines for Artificial Intelligence Medical Device included a specific section to flesh out requirements for cybersecurity and data protection associated with AI medical devices.
- The Ministry of Science and Technology published the Implementing Rules of Administrative Regulations on Human Genetic Resources Management (Draft for Comments) in April 2022, which beefed up regulations on collection, preservation, utilisation and provision of human genetic resources derived from China ("China HGR") for non-clinical purposes, especially prohibiting foreign entities or individuals from collecting or preserving China HGR or providing China HGR abroad.

## Prospects and Challenges

With the continuous and strong support from the Chinese government and the accelerated adoption of emerging technologies in various healthcare sectors, China's digital healthcare industry has entered into a golden period of development. It is expected that the Chinese government will maintain its supportive policies for the digital healthcare industry in the coming years, and consumers' demand for intelligent, personalized and efficient healthcare services will continue to rise. According to statistics, the market size of China's digital healthcare industry is expected to exceed RMB1.5 trillion by 2025.

Despite the promising future of China's digital healthcare, however, the following major issues and challenges with the business models and legal frameworks remain to be improved.

### *Market access*

Laws and regulations do not always keep up with innovative applications of new technologies in the healthcare sector. Consequently, relevant market players usually have to keep in close communication with regulatory authorities on a case-by-case basis in order to realise the commercialisation of novel products and services as well as reduce compliance risks.

### *Data protection*

The enormous amount of data generated in the digitalisation of the healthcare sector are sensitive and valuable resources that will be subject to the supervision of various governmental authorities, posing a challenge to the coordination among multiple supervisors which requires clearer guidelines in this regard.

Furthermore, healthcare data leakage and infringements are not uncommon in practice, mainly due to the absence of a specific, comprehensive and operable legal framework for healthcare data protection. Thus, it remains difficult for individuals to pursue appropriate remedies and compensation through effective legal proceedings.

### *Liability*

The existing liability framework may not be able to provide suitable and effective remedies for infringements related to novel digital healthcare services and products. For example, if medical accidents occur when using AI diagnostic tools or surgical robots, how to determine and allocate

the liabilities among developers, manufacturers and physicians is still a practical challenge.

### *Payment methods*

Currently only costs related to limited digital healthcare services are covered by medical insurance funds and the roadblocks for expansion to reimbursement by medical insurance funds remain to be lifted.

**Han Yi Law Offices** is a leading boutique law firm in the private equity investment community in the People's Republic of China (PRC), specialising in the formation and deployment of private equity and venture capital funds, M&A, securities, banking and finance and foreign-related dispute resolutions. With a team of 20 lawyers at its Shanghai offices, the firm regularly represents world-class private equity investors, venture capitalists, active industrial investors, hedge funds and PRC state-owned investment arms. Han Yi Law advises on a wide variety of private equity transactions, including buyouts (leveraged and non-leveraged), early and late-stage venture investments, restructurings, privatisation and recapitalisations and exit transactions. The firm has a proven track record in structuring and executing innovative and complex cross-border private equity and venture capital investment deals and M&A transactions involving buyouts, follow-on acquisitions, IPOs and trade sales, among others.

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