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China: Trends & Developments

Linda He and Zoe Zhang
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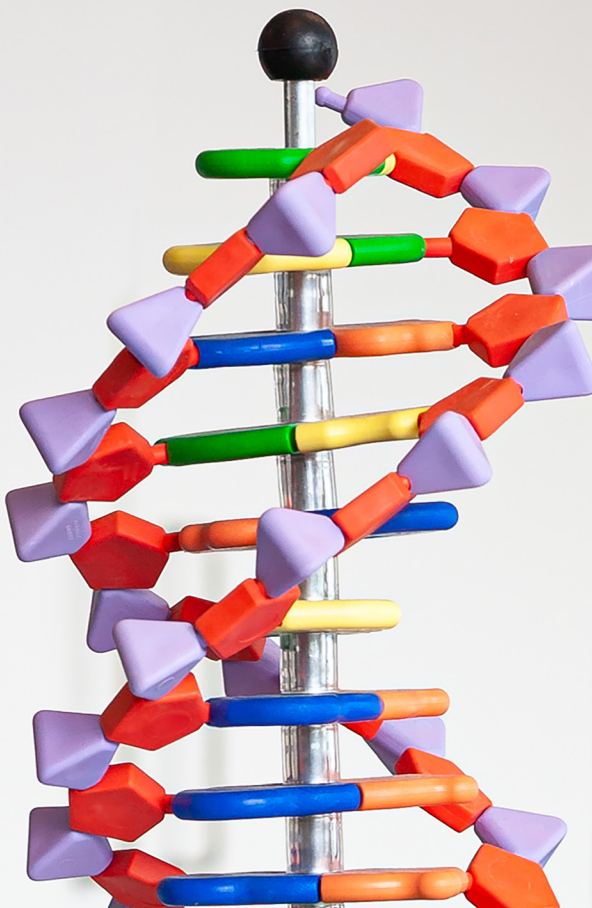

CHINA

Trends and Developments

Contributed by:
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Han Yi Law Offices is one of the most active and knowledgeable resources in the PRC private equity investment community, and is a leading Shanghai-based Chinese boutique law firm specialised in formation and deployment of private equity and venture capital funds, M&A, securities, banking and finance, and foreign related dispute resolutions. With around 20 lawyers, Han Yi Law Offices regularly represents world-class private equity investors, venture capitalists, active industrial investors, hedge funds and PRC state-owned investment arms targeting essentially all major industry areas in a wide variety of private equity transactions, including buyouts (leveraged and non-leveraged), early and late-stage venture investments, restructurings, going private and recapitalisations, and exit transactions. The firm has a proven track record of 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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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 pharmacies, 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 has improved 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 delivery, and online payment, as well as medical insurance reimbursement services. By the end of 2022, the Chinese government had approved a total number of 2,700 internet hospitals, with the number of users of internet-based medical services in China reaching 363 million. The market size of internet hospitals and online pharmacies reached around RMB310 billion and RMB250 billion respectively, representing an increase of approximately 39% and 36% correspondingly, on a year-on-year basis. However, it remains unclear whether the demand for internet hospitals and online pharmacies boosted by the COVID-19 pandemic will continue to rise in the post-COVID-19 era.

The boom of investments in China's digital healthcare industry in 2021 was subsequently followed by a slowdown in 2022 along with the economy's downturn in general. According to statistics, the total financing amount in the main sectors of China's digital healthcare industry (eg, internet hospitals and online pharmacies) in 2022 was approximately RMB4 billion, down by over 80% on a year-on-year basis, while the total number of financing transactions declined by around 40%.

New Technologies and Applications

With 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 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 these 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 policies promoting "Internet Plus Healthcare".

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

- Online diagnosis and treatment services – which under applicable laws and regulations are generally limited to online diagnosis, treatment and prescription services for subsequent visits of outpatients. 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 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 the fact that large internet healthcare platforms saw a significant rise in their revenues in 2021 and 2022 (especially revenue from the online sale of drugs), their profitability remains relatively low compared to offline services, as the unit price of online services and consumers' willingness to pay for them are also still relatively low and the homogeneity competition in this sector has become quite severe.

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 (CDSSs), drug development and health management, with a prominent area being imaging auxiliary diagnosis. In 2022, the Ministry of Science and Technology (MOST) issued several polices to promote the application and innovation of AI technology in the healthcare industry.

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 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. In 2022, the number of approved AI medical software reached a record

high with a total of 25 Class III medical device licences issued by the NMPA.

With the advent of more advanced applications of AI technology (eg, the launch of ChatGPT) in 2022, development of AI-doctor products providing diagnosis and treatment services has captured the market's attention. It is reported that some online healthcare companies in China will soon launch their first AI-doctor products in the market. As China's existing regulations specifically prohibited AI from replacing physicians to provide diagnosis and treatment services, the legal basis and framework for the commercialisation of AI-doctor products is still pending further clarification from China's authorities.

Medical robots

The use of medical robots in China has been growing rapidly since 2019, and they have been applied in various healthcare scenarios (eg, medical guidance, surgery, rehabilitation and nursing) to enhance 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. With the aim of boosting application and funding of medical robots, China issued a series of supportive policies in 2021–2022 in this sector, benefiting medical robot market players and consumers.

According to statistics, in 2022 the NMPA approved over 15 domestic surgical robots, twice the number of those approved in 2021; and the market size of China's surgical robots is expected to reach RMB12 billion by 2023.

Smart hospitals and 5G

With the aim of optimising medical services and streamlining diagnosis and treatment, China released a series of supporting policies for building smart hospitals in 2022, which are based on the implementation of electronic medical records (EMRs) systems and other information systems. The application of smart hospital solutions has gradually become a key performance assessment and evaluation indicator for public hospitals in China.

5G technology plays a crucial role in the construction of smart 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. In September 2021, China's Ministry of Industry and Information Technology (MIIT) and the National Health Commission (NHC) announced the "5G+ Medical Health" pilot projects, which are aimed at fostering innovative products and business models in the 5G medical healthcare industry. It is expected that 5G network coverage will become one of the main goals for hospital infrastructure upgrades.

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, compliance data sharing and whole-process traceability of healthcare data. In recent years, the NHC and its local counterparts have been making efforts to set up a nationwide healthcare data infrastructure (eg, an all-citizen health information platform and medical health big data centre) by using big data and blockchain technologies with the intention to facilitate interconnectivity and information sharing between hospitals.

In May 2022, a national unified medical insurance information platform was established, with an effort to facilitate information sharing between social insurance authorities and medical institutions at all levels across the country. It is expected that all public medical and health institutions in China will get connected to this national health information platform by 2025.

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 MIIT issued a strategic plan in 2021 to propose the development of new products in the field of "3D printing plus medical health" and the promotion of customised medical services and devices such as rehabilitation equipment, implants and soft tissue repairing treatment. Some provincial governments have gone further and have set up pricing guidance and policies for medical 3D printing devices in an effort to ensure costs related to medical 3D printing are covered by local medical insurance and are more affordable for patients.

Digital therapeutics

Digital therapeutics (DTx) is a relatively new concept in the digital healthcare industry, and generally refers to evidence-based medical interventions driven by software programs for disease prevention, management and health improvement. As DTx products may also apply AI technology, there could be an overlap between DTx products and AI-based medical devices.

DTx has attracted market attention in China in recent years, with an increasing number of DTx products obtaining medical device licences and being launched in the market. It is noteworthy, however, that the definition, classification and technical criteria of DTx remain unclear under China's existing regulatory framework. To duly address these issues, the NMPA was reported to have organised a meeting with experts to discuss and study the DTx field at the end of 2022; and regulatory guidelines for the DTx sector are expected to be released in due time.

Major Regulatory Developments in the Digital Healthcare Sector

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

Foreign investment

The Chinese government has continued its efforts to further open the digital healthcare sector to foreign investors in recent years. 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 Telecommunications Business Licence.

However, with respect to businesses 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 (see Healthcare data protection for more details).

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 the Chinese internet healthcare industry also sprang up, including:

- online malpractice by disqualified physicians;
- online diagnosis by AI rather than by 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 officially released the *Detailed Rules for Regulation of Internet-based Diagnosis and Treatment (Trial)* in June 2022, 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.

It is also worth noting that the *Circular on Boosting the Provision of Internet-based Medical Services for COVID-19* issued by the NHC in December 2022 conditionally allowed internet hospitals to provide first-time diagnosis and treatment of COVID-19-related symptoms. The market generally expects that first-time diagnosis and treatment of more types of common and chronic diseases may be available online in the future.

Furthermore, the National Healthcare Security Administration and the NHC have released a series of supportive policies in terms of pricing management of and medical insurance reimbursement for "Internet Plus Healthcare" services. The National Development Reform Commission also issued an implementation plan in December 2022, further clarifying that certain internet medical services will be included in the scope of China's medical insurance payment system. 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, decision-supporting software, treatment planning software, rehabilitation training software, etc) 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 whether 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 applications, 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 on 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 a physician's decision-making) and its algorithm maturity. In March 2022, the NMPA released three guidelines further streamlining and optimising China's review and approval system for AI-based medical devices:

- 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*.

In addition, the NMPA successively released several guidelines in 2022 to further specify the requirements for registering certain typical AI medical software products.

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 throughout various general laws and regulations, as well as throughout 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 classified personal information on medical health as "sensitive personal information" which should be afforded a higher level of protection than ordinary personal information.
- The *Data Security Law* and the *Administrative Regulations on Network Data Security (Draft for Comments)* issued in June and November 2021 respectively, proposing to establish a data classification and graded protection scheme, through classifying data as "important data", "core data", and "general data" and requiring corresponding protection measures to be taken for different categories of data. It is noteworthy that genetic and other healthcare data that meet a certain scale or accuracy level (eg, data concerning more than one million pieces of personal information) as required by relevant authorities are classified as "important data" (detailed catalogues of "important data" are yet to be formulated) and thus will subject the data processors to some special protection requirements for "important data".
- The *Measures for Network Security Review and the Measures for Security Assessment of Outbound Data Transfers* released in December 2021 and July 2022, respectively, further required that healthcare data processors must apply for a government-led security

review or assessment in any of the following circumstances:

(a) outbound transfer of "important data" by a data processor;

(b) outbound transfer of personal information by a Critical Information Infrastructure Operator (CIIO; the guidance on identifying such operators remains to be further clarified) or a data processor who has handled more than one million pieces of personal information;

(c) outbound transfer of personal information by a data processor who has provided personal information of 100,000 people abroad cumulatively or sensitive personal information of 10,000 people abroad cumulatively in the previous year;

(d) listing abroad by a healthcare data processor who has handled more than one million pieces of personal information; and

(e) any other data processing activity which has or may have national security concerns.

- The *Detailed Rules for Regulation of Internet-based Diagnosis and Treatment (Trial)* released in June 2022 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 systems. They should also establish internal mechanisms and enter agreements with relevant partners in relation to cybersecurity, personal information protection and data use management.
- The *Administrative Measures for Cybersecurity of Medical and Healthcare Institutions* issued in August 2022 further detailed the network and data security protection obligations of medical institutions as network operators, CIIOs and data processors, providing more practical guidelines for medical institutions in terms of compliance with existing regulations on network and data security.
- The MOST published the *Implementing Rules of Administrative Regulations on Human Genetic Resources Management* in June 2023, 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 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, personalised 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.

Data protection

The various types and enormous amount of data generated in the digitalisation of the healthcare sector (including EMRs, clinical trial data, health information, human genetic resources, healthcare big data, etc) are sensitive and valuable resources that will be subject to the supervision of various governmental authorities, posing a challenge to the co-ordination of multiple

supervisors, and requiring 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.

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.

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, the determination and allocation of 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 regarding expansion to reimbursement by medical insurance funds remain to be lifted.

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