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Investing in personalised health in China

Personalised healthcare is reshaping the pharmaceutical industry on a global scale. China, in particular, is embracing this change with its Healthy China 2030 strategy and its drive to reform the medical and healthcare landscapes. Investments reflecting the core principles of the strategy and which facilitate the implementation of personalised healthcare are likely to be met favorably. However, regulatory reform also needs to align to this desire. What are the key factors that should be front of mind for business leaders and foreign investors in the sector in China?

Chinese regulation and law strives to keep up with technological change

Innovation in the healthcare market is increasing at a rapid rate, with the Chinese regulatory framework responding accordingly. In particular, regulation is changing specifically to address new technologies (eg, AI) and big data that are key considerations to companies adopting personalised health approach.

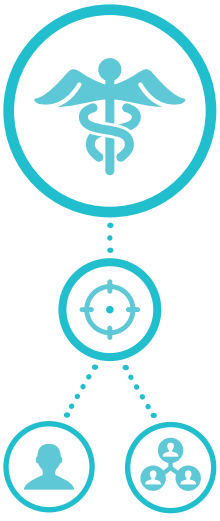
This shift in regulation can be seen in:

- The State Council in June 2016 issuing "Opinions on Promoting and Standardizing the Application and Development of Health Care and Medical Big Data". This seeks to establish a regulatory framework for sharing and protecting big data in the healthcare and medical sectors, and in doing so, implement a structure for sharing big data across relevant governmental departments and public institutions.
- The Chinese Food and Drug Administration ("CFDA") in October 2017 releasing for public consultation the "Draft Amendment of the Drug Administration Law" and the "Draft Administrative Measures for Drug Registration".

These consultation documents show that it is a priority of the Chinese government to reform the rules governing the approval of new medicinal products in China, particularly where those new products result in enhanced innovation in China.

Even though the State Council's Opinion and the CFDA's public consultation on its proposed new rules

Personalised healthcare

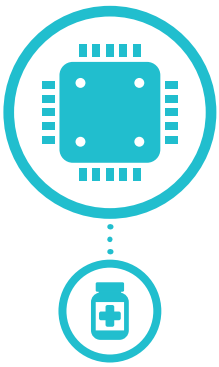


personalisation of healthcare either to a specific individual or a group of patients

Precision medicine

the tailoring of medicine or therapies to individuals or groups of individuals

Smart healthcare



the use of technology in the improved healthcare delivery or quality of life

do not directly affect the existing regulations for foreign investment, what they demonstrate is the government's support of the growing Chinese pharmaceutical and healthcare markets. Given this, we expect that the Chinese government will implement various measures to promote the openness of the Chinese pharmaceutical and healthcare markets and to facilitate foreign investment, with the ultimate aim of utilising new technologies and big data to improve industry practice and healthcare in China. In parallel, data protection and IP laws are also evolving to account for these technological advances and increased use of data.

Below are some key factors that need to be considered by business leaders and foreign investors interested in the pharmaceutical sector and personalised health in China.

Pharmaceutical Regulations

Patent transparency

Although still subject to public consultation through a soliciting opinion, the Chinese Government is intending to implement changes under which the Chinese regulatory system will adopt a system of "patent linkage" (ie, the CFDA will consider patent rights when approving medical products). In this new system, the party seeking approval must not only disclose to the CFDA all patents that may be relevant to their medical product, including the status of each patent, but also notify the relevant patent holder of their application. As a consequence, rights holders will be put on notice of potential infringement and be able to respond accordingly. Furthermore, upon confirmation from the judicial authorities that patent infringement proceedings have been commenced, the CFDA will stay the approval process for a period of up to 24 months.

Regulatory protection for early entrants

In the same soliciting opinion, similar to several other jurisdictions, China is intending to grant periods of regulatory protection ranging from 1.5 to 10 years under which clinical data submitted for a new medical product cannot be used by third parties to seek approval of generic or biosimilar medicinal products that they have developed without the consent of the rights holder in the data submitted for the original product.

The rapidly evolving Chinese healthcare market, supported by China actively embracing technology and a smart healthcare approach, gives rise to a number of key opportunities and considerations for foreign investors.

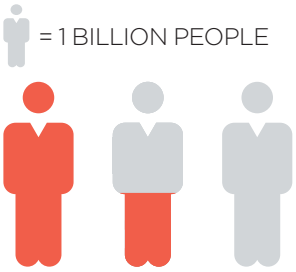
Protection of sensitive, personal data is critical

The use of precision medicines in many instances will require the handling of patients' sensitive, personal data. To the extent that this needs to be disclosed to the CFDA (or other government agency) as part of the requirements for marketing approval or market access, compliance at all times with the relevant data protection laws and rules (ie, the Cybersecurity Law and Personal Information Security Specification) will need to be carefully considered.

M&A regulation – foreign investment restrictions

Investment access considerations

Amongst other things, the latest restrictions governing foreign investments in China (the Special Administrative Measures for Access of Foreign Investments (Negative List), 2018 Edition), prohibit direct foreign investment in the processing of traditional Chinese medicine decoction pieces and the production of Chinese patent medicines with a secret formula. The restrictions do permit indirect investment in medical institutions by permitting investment in joint ventures involving Chinese entities (either through shareholdings in such joint ventures or through contractual agreements) that have been approved by the Ministry of Commerce (MOFCOM) or one of its local branches. Foreign investment in other areas of



IN 2015, CHINA'S POPULATION WAS ESTIMATED AT 1.4 BILLION PEOPLE

AVERAGE LIFE EXPECTANCY OF 76.5 YEARS

HEALTHCARE SPENDING REPRESENTS 5.9% OF CHINA'S GDP AT $640 BILLION

HEALTHCARE EXPENDITURE WILL DOUBLE BY 2020 TO AROUND $1.1 TRILLION

healthcare only requires the investment to be recorded with MOFCOM by the completion of the relevant online filing. As a consequence, it is important that all foreign investors consider and comply with the applicable foreign investment restrictions.

M&A consideration – intellectual property rights

IP issues arising from the development of personalised health products

Personalised health, especially smart healthcare, heavily relies upon data and computer systems to provide personalised diagnosis and treatment. This may require pharmaceutical companies to enter into collaborations, joint ventures or use specialist contractors, such as software companies, to develop the required IT systems, software and infrastructure. It is critical that the ownership and ability to use all relevant IP rights is properly understood as part of the due diligence process to ensure that these are acquired as part of the transaction.

Availability and limits of IP protection

Unlike most existing medicinal products, for which patent rights represent the most valuable IP right, a more diverse set of IP rights is likely to be relevant to the protection of personalised health products (eg, database rights and copyright in software). As a consequence, it is important to understand the availability and limits of each of those rights, particularly where these relate to emerging technologies (eg, Artificial Intelligence) where the Chinese IP law is evolving to deal with these new developments.

M&A consideration – data protection

Cybersecurity is critical to data protection and creates a higher cost of entry

Personal, sensitive data (medical and consumer) is key to the personalised health market. Given this, it is vital to properly consider cybersecurity issues and consumer protection concerns as part of the due diligence process. In 2016, the Cybersecurity Law was issued which imposes strict measures that must be complied with. Furthermore, on 11 April 2017 the relevant Chinese authority (The State Internet Information Office) published specific measures following the implementation of that law in relation to the transfer of data outside of China. These measures, the Measures on Security Assessment of Cross-border Transfer of Personal Information and Important Data (Draft for Soliciting Opinion), impose stringent obligations in relation to transferring data outside of China. Foreign investors need to account for these restrictions when considering their commercial aims and whether the restrictions would preclude them from globalising any product or service developed in China.

The rapidly evolving Chinese healthcare market, supported by China actively embracing technology and a smart healthcare approach, gives rise to a number of key opportunities and considerations for foreign investors. Keeping abreast and responding to these legal and regulatory changes will be vital to ensuring successful investments in China or collaborations with Chinese entities.

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