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Medical Devices & Consumer Health Products 2022

China: Law & Practice

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CHINA

Law and Practice

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Product Safety Regulatory Regime for Medical Devices

Classification of medical devices

Under the PRC legal regime, "medical devices" refers to instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or relevant articles including necessary computer software that are directly or indirectly used for the diagnosis, prevention, monitoring, treatment or relief of diseases or injury, the functional compensation of injuries, the inspection, substitution, adjustment or support of physiological structures or physiological processes, the control of pregnancy or the support or maintenance of life. Unlike a pharmaceutical, the utility of medical devices is mainly achieved by physical or other means rather than pharmacological, immunological or metabolic means, or where the latter means only act as auxiliary functions. "Medical instrument" is not a legally defined term under the PRC laws. Generally, medical instruments would be interpreted as being the same as medical devices.

Activities relating to medical devices have been strictly regulated in the PRC, and the regulations that apply to a medical device in the PRC depend on how that medical device is classified. Medical devices are categorised into three classes according to their risk levels. The National Medical Products Administration (NMPA) determines a medical device's risk level according to its intended purposes, structural features, the form of use, whether it is in contact with or has access to the human body, and other factors. In general, Class I medical devices refer to those that have a low degree of risk and whose safety and effectiveness can be ensured through routine administration, and therefore they are merely subject to a record-filing administration under the supervision of the NMPA and its local counterparts; Class II medical devices refer to those with a medium degree of risk; and Class III medical devices refer to those with the highest risk level, the safety and effectiveness of which need to be ensured by strict control and regulation, and which therefore are subject to registration administration under the supervision of the NMPA. The NMPA has issued the *Rules for Medical Device Classification* and the *Catalogue of Medical Device Classification* to guide this classification of medical devices.

Regulations of medical devices

The *Regulations for the Supervision and Administration of Medical Devices* (RSAMD) set up the regulatory framework for the administration of medical devices. The development, registration, manufacturing and distribution of medical devices are regulated by more detailed GxP rules and administrative measures, such as Good Manufacturing Practice, Good Clinical Practice and Good Supply Practice for Medical Devices.

Subject to the classification of the medical devices, the registrants or the record-filing holders of the medical devices (ie, the marketing authorisation holders (MAHs) of the medical devices) are responsible for the quality management of the whole life cycle of medical devices and are responsible for the safety and effectiveness of medical devices in the whole process of the development, manufacturing, distribution and use of such medical devices according to applicable laws and regulations. Those who wish to engage in clinical trials or the manufacturing or distribution of medical devices must also obtain a permit or approval, which is discussed in **2. Commercialisation and Product Life Cycle**.

Software-Based Medical Devices

Please see **1.3 New Products/Technologies and Digital Health**.

Product Safety Regulatory Regime for Pharmaceuticals (Including Blood Products)

"Pharmaceuticals", "medicines" and "drugs" refer to substances that are used to prevent, treat or diagnose human diseases and are intended to regulate human physiological functions, for which the usage and dosage are specified for indication or primary treatment. The fundamental law regulating pharmaceuticals in China is the *Drug Administration Law*, which governs various drug-related activities, including their development, registration, manufacturing and distribution. Under the PRC legal regime, pharmaceuticals and medical devices are categorised as two different types of products subject to different regulations. Details on the regulation of pharmaceuticals can be viewed in the Chambers Global Practice Guide for Life Sciences.

Under the PRC legal regime, blood products refer to, in particular, various human plasma protein products, which are governed as pharmaceuticals.

Product Safety Regulatory Regime for Personal Protective Equipment

"Personal protective equipment" is not a defined legal term under PRC laws.

There are specific requirements for "special labour protection articles", which include safety nets, safety helmets, building fasteners and other products that ensure labour safety. The current regulations on special labour protection articles are less stringent than the regulations for medical devices. Unlike medical devices, business operators do not need to obtain special permits or licences for the registration, manufacturing or distribution of special labour protection articles. The government implements a third-party voluntary certification system for attaching safety signs on special labour protection articles, and the production, circulation and use of such special labour protection articles are subject to enhanced supervision by Administration for Market Regulation and its local counterparts (collectively, AMR) beyond ordinary products, by means of spot checks of product quality and on-site supervision for the use of such special labour protection articles.

If the protective articles used by medical staff fall within the scope of medical devices, they are regulated as medical devices.

General labour protection articles and other personal protective equipment are deemed to be ordinary products with no special regulatory requirements for their marketing, manufacturing and distribution.

1.2 Healthcare Products

Product Safety Regulatory Regime for Healthcare Products

Cosmeticsare governed by administrative regulations, ranging from manufacturing to marketing, business operation and post-market monitoring. The *Regulations on the Supervision and Regulation of Cosmetics* are the most significant regulations in the hierarchy, which apply a Classification Supervision System to cosmetics:

- special cosmetics, referring to cosmetics that claim new efficacy, must be registered with the competent authorities before manufacturing and import; while
- ordinary cosmetics (cosmetics other than special cosmetics) need only be record-filed.

Biocides fall under the legislative regime of pesticides and thus must comply with the strictly regulated system for pesticides. According to the *Regulations on Pesticide Administration*, for the manufacturing, marketing and business operation of pesticides, corresponding licences must be obtained from the competent authorities. Post-market monitoring of pesticides is also a highly regulated area.

Food and nutrition supplements are regulated under the *Food Safety Law*. To be specific, food is classified as either conventional food or special food, and the latter covers health food. Health food refers to food with specific healthcare functions, which means food that is suitable for specific groups of persons due to its functions for body regulation but not for the purpose of disease treatment, and includes nutrition supplements. Thus, nutrition supplements must follow the *Food Safety Law* and, meanwhile, are subject to special regulations for health food, which are named the Catalogue Management System under *Administrative Measures for the Catalogue of Ingredients* and the *Catalogue of Healthcare Functions of Health Food*.

1.3 New Products/Technologies and Digital Health

Certain medical apps, telemedicine information systems and wearables may be classified as medical devices if they meet the definition of a medical device as discussed in **1.1 Medical Devices**.

Medical Apps

A medical app is a kind of medical device software if it meets the definition of a medical device as discussed in **1.1 Medical Devices**. Medical device software can be divided into two main categories: standalone software and software components.

Standalone Software

Standalone software refers to software intended to be used for one or more medical purposes that performs these purposes without being part of a hardware medical device. There are two types of standalone software: generic standalone software and dedicated standalone software.

Generic standalone software

Generic standalone software is usually used in conjunction with multiple medical devices based on a generic data interface, such as medical image processing software and patient monitoring software. Generic standalone software is generally registered as a medical device.

Dedicated standalone software

Dedicated standalone software is linked to a specific medical device based on a generic or dedicated data interface, which could be registered either as an independent medical device or as a part of a hardware medical device. If registered as a part of a hardware medical device, it will be regarded and regulated as a software component, rather than as a medical device.

Software Components

"Software component" refers to software that is intended to be used for one or more medical purposes and that controls or drives a hardware medical device or runs on a dedicated/medical computing platform. A software component is a component of a medical device that does not need to be independently registered as a medical device but should be registered along with the medical device it works with.

Wearables

Wearables that meet the definition of medical devices as discussed in **1.1Medical Devices** are classified and regulated as medical devices. Otherwise, they are regulated as electrical or electronic products, such as massagers, exercise machines and heart rate monitors for exercise.

Telemedicine

A telemedicine information system is used for telemedicine services. According to Good Practices for Telemedicine Services (for Trial Implementation), the telemedicine information system shall ensure that images, sounds, texts and other medical information required in the telemedicine service can be transmitted safely and in time, and ensure that the images are clear and that

the data is accurate. The telemedicine information system must also conform to the Technical Guidelines for Construction of the Telemedicine Information System and meet the requirements of clinical diagnosis.

Equipment in the telemedicine information system that meets the definition of a medical device is regulated as a medical device.

Cannabidiol

Cannabidiol (CBD) is an active ingredient of cannabis which cannot be used as a raw material for cosmetics in accordance with the List of Prohibited Raw Materials for Cosmetics issued by the NMPA. Furthermore, cannabidiol is not listed in the *Catalogue of Narcotic Drugs*, the *Catalogue of Psychotropic Substances* or the *Supplementary Catalogue of Controlled Narcotic Drugs and Psychotropic Substances for Non-pharmaceutical Use*.

1.4 Borderline Products

Medicines and Medical Devices

Generally, medicines and medical devices are two types of products with similar stringent regulation methods. The MAH of medicines or the medical device registrants/record-filing holders are responsible for the whole life cycle of the product.

In practice, certain types of products may have features of both medicines and medical devices and will be categorised as either medicines or medical devices depending on the characteristics of such products.

- *A combination product*. As to a medical product containing both a drug and a device (ie, a combination product), applicants should apply for its registration as a drug if it mainly acts as a drug and should apply for its registration as a medical device if it mainly acts as a medical device. If its major utility cannot be easily identified, the applicant should apply to the Centre for Medical Device Standardisation Administration of the NMPA in order to define the characteristics of such combination product before applying for its registration.
- *In vitro diagnosis (IVD) reagents*. Under the PRC legal regime, most IVD reagents, including reagents, kits, calibrators and quality control products used for in vitro testing of human samples in the process of disease prediction, prevention, diagnosis, treatment monitoring, prognosis observation and health status evaluation, are defined as medical devices, except for IVD reagents for blood source screening and IVD reagents labelled with radionuclides, which are characterised as drugs.

Personal Protective Equipment and Medicines

Personal protective equipment and medicines are different categories of products under different types of regulations. As mentioned in **1.1 Medical Devices**, the protective articles used by medical staff that fall within the scope of medical devices are regulated according to the rules for medical devices.

Medicines and Food

Consumers may confuse health foods with medicines because health food may claim certain functions of health protection. However, the *Food Safety Law* stipulates that food, including health food, excludes substances that are used for the purpose of treatment and further stresses that labels and descriptions of health food shall not refer to any preventive or therapeutic function but shall instead state that they cannot replace medicine.

2. COMMERCIALISATION AND PRODUCT LIFE CYCLE

2.1 Design and Manufacture

Requirements on Manufacturing Medical Devices

The manufacture of medical devices either for clinical use or for commercialisation must comply with the requirements of the RSAMD, the *Measures for the Supervision and Administration of Medical Device Manufacture*, and Good Manufacturing Practice for Medical Devices ("GMP for Medical Devices") in the PRC. GMP for Medical Devices contains general requirements regarding organisation and personnel, premises and facilities, equipment, document management, design and development, purchasing, manufacturing management, quality control, distribution and after-sales services, control of nonconforming products, monitoring, analysis and remediation of adverse events, and other specific requirements for specific products, as appendices.

Among others:

- for manufacturing sites, the premises must meet the manufacturing requirements, eg, the production area must be of sufficient capacity to suit the scale of production and the varieties of the products, and the overall layout of the production, administrative and ancillary areas must be reasonable and they must not interfere with each other;
- for design and development planning, a manufacturer must set out the design and development stages as well as the review, verification, validation and design transfer activities to be performed at each stage. The design and development inputs must include the functional, performance and safety requirements according to the intended purpose, regulatory requirements, risk management and control measures and other requirements. Design and development outputs must meet the input requirements, including the relevant information needed for purchase, manufacture and services, product technical requirements, etc;
- the manufacturer must keep legible and complete records that ensure the traceability of activities such as the manufacture and quality control of the products; and
- unless otherwise specified by the applicable laws or regulations, all the records must be retained for a period at least equivalent to the life span of the medical device and for not less than two years from the date of release of the product.

In addition to the above-mentioned GMP requirements, the manufacturer of medical devices must obtain a licence or record-filing before it manufactures medical devices for commercialisation. The requisite permits for manufacturing medical devices vary based upon the classification of the medical devices to be manufactured. For manufacturing Class I medical devices, a manufacturing record-filing receipt is required. For manufacturing Class II and/or Class III medical devices, a licence must be obtained.

Contract Manufacturing of Medical Devices

Except for the medical devices listed in the *Catalogue of Medical Devices Prohibited from Entrusted Manufacturing*, the MAH of medical devices can entrust a qualified third-party manufacturer to manufacture the medical devices. In such a case, the parties must enter into an agreement to prescribe the responsibilities of each party and especially the responsibilities and liabilities for product quality assurance. The manufacture of a medical device can only be entrusted to one manufacturer (except for the holding company) during one period, and such entrustment must be filed or registered to be valid and enforceable.

Healthcare Products

A licence for manufacturing is a prerequisite for production of cosmetics and food. Manufacturers of cosmetics and food must follow the respective manufacturing requirements.

Good Manufacturing Practice for Cosmetics ("GMP for Cosmetics") is a general guideline for cosmetics manufacturers to develop an internal quality control system, which, in turn, is the standard for competent authorities to inspect whether the manufacturing qualifies. Key aspects of GMP for Cosmetics include organisation and personnel, quality assurance and control, management of factory facilities and equipment, management of material and product, manufacturing process management, management of entrusted manufacturing and management of product sales.

Food production must conform to the requirements stipulated by the *Food Safety Law* and a whole set of national standards regarding food safety. Key requirements include the establishment of the internal food safety management system, the self-inspection system for food safety and implementation of controls over raw materials, self-control concerning the production process, safety of equipment, storage and packaging, as well as inspection and control over finished products, transportation and delivery.

Special Regulations for Medical Apps

With respect to medical apps, the NMPA has issued special regulations for the manufacture of standalone software, such as the *Appendix for Standalone Software to GMP for Medical Devices* (the "Appendix"), and *GMP for Medical Devices – Guidelines for On-Site Inspection of Standalone Software*.

The Appendix applies to standalone software and applies mutatis mutandis to software components. According to the Appendix, the special requirements cover aspects including personnel, equipment, design development, procurement, manufacturing management, quality control, sales and after-sales service, and monitoring, analysis and remediation of adverse events.

To be more specific, (i) concerning quality control, the Appendix requires that the release of software products is documented, and software version identification, installation and uninstallation testing, product integrity inspection and other activities related to the quality control of software products must also be recorded; and (ii) with respect to design specifications, the Appendix requires that the software design specifications and relevant review records are formulated and approved and updated in due time.

Special Rules and Standards for Wearables

For wearables that meet the definition of medical devices and are regulated as medical devices, the Centre for Medical Device Evaluation (CMDE) of the NMPA has issued several technical guidelines and product registration guidance for certain medical device wearables, such as pulse oximeters.

As for wearables that are electrical or electronic products rather than medical devices, several national standards on electrical or electronic products may apply, such as GB/T37344, GB/T37035, GB/T37037, GB/T41265, etc.

Furthermore, wearables using GSM/GPRS, CDMA, CDMA1X, CDMA2000, TD-SCDMA, WCDMA and TDLTE standards must obtain CCC certification.

2.2 Corporate Social Responsibility, the Environment and Sustainability

There is a national trend towards strengthening the legislation on corporate social responsibility. Entities involved in the life cycle of medical devices and healthcare products must undertake

general statutory obligations for environmental protection under the framework of Environmental Protection Law of the PRC, such as reducing the discharge of pollutants, and must ensure the establishment, operation and improvement of their environmental management systems; besides, the manufacturer must apply for a pollutant discharge permit or fill in a pollutant discharge registration form.

For wearables that are electrical or electronic products, the State Council of the PRC has issued the *Regulation on the Administration of the Recovery and Disposal of Waste Electrical and Electronic Products*, which requires that the producers of electrical and electronic products, the consignees of imported electrical and electronic products or their agents produce or import electrical and electronic products legally based on the pollution control applied to electrical and electronic products, adopt design plans favourable to comprehensive resource utilisation and innocuous disposal, and use non-toxic, non-hazardous, low-toxicity or low-hazard materials that can be conveniently recycled.

In addition,China is currently establishing standards with more specific requirements for healthcare products in respect of environmental protection, including the Water Pollutant Discharge Standard for Pesticide Industry (Second Draft for Comment) (2022), the Water Pollutant Discharge Standard for Cosmetics Industry (Draft for Comment) (2010), and the Cleaner Production Standard for Daily Use Chemical Industry (Cosmetics) (Draft for Comment) (2008).

2.3 Advertising and Product Claims

General Restrictions on Advertising of Medical Devices

The advertising of medical devices is subject to stricter requirements than the advertising of general goods. Other than the general *Advertising Law of the PRC*, the *Interim Administrative Measures for Examination of Advertisements for Drugs, Medical Devices, Health Foods and Foods for Special Medical Purpose* also set out detailed requirements regarding how medical devices are advertised and the content of such advertisements. According to these advertising laws and regulations, medical devices that are used for the treatment of addiction or whose production, sale or use is ceased or prohibited according to the applicable laws are prohibited from being advertised. In addition, advertisements for medical devices are not allowed to be published in public media that target minors.

Further, advertising of medical devices is subject to the prior examination and approval of the relevant local authorities under the SAMR, and a unique approval number must be obtained. The advertisement must clearly indicate such approval number. Generally, any activities and behaviour that directly or indirectly introduces or recommends a medical device through the use of a certain medium may constitute an advertisement that is subject to such prior approval, unless only a product name is publicised in the advertisement; in such a case, prior approval is not required.

Content of the Medical Device Advertisement

As a general principle, all advertisements must be true and lawful and must not contain any false or misleading content. Advertisers are responsible for the veracity and legitimacy of the content. Also, an advertisement must not be used for any unfair competition activities; for example, the advertiser must not discredit competitors in an advertisement.

As to the advertisement of a medical device, the contents of a medical device advertisement must conform with the contents of the registration certificate or filing certificate, or the registered or filed product instructions approved by the competent authority. Where the medical

device advertisement involves the name, scope of application, functional mechanism or structure or composition, etc of the medical device, the publicised information must not exceed the scope that has been approved in the registration certificate or filing certificate or registered or filed product instruction. Advertisements of medical devices recommended for self-use by individuals must prominently display the following words: "Please read the product instruction carefully or purchase and use the product under the guidance of a healthcare practitioner." Where there are contraindications and precautions in the registration certificate of the medical device, the advertisement must also prominently display these words: "Please refer to the product instruction for contraindications or precautions in detail."

Among other restrictions that apply to the content of advertisements in general (eg, no content stating that the product is of the highest level is allowed), the following are the specific restrictions that apply to advertisements for medical devices:

- they must not use the name or image of any patient, health technician, medical education or scientific research institution or its personnel or other public association or organisation as an endorsement;
- they must not contain guarantees of the medical device's efficacy or the cure of disease, or guarantees by implication of the cure of disease; and
- they must not contain any inducements such as "hot sales", "rush to buy", "trial", "family necessities", "free treatment", "free gifts", or any comprehensive evaluations such as "comparison", "ranking", "recommendation", "designated", "selected", "awards", or any warranties such as "refund upon ineffectiveness", "insured by insurance companies".

Healthcare Products

All commercial advertisements introducing healthcare products directly or indirectly are subject to the *Advertising Law*. The fundamental principle is that the contents of advertisements shall be true and accurate, and shall not contain any false or misleading information. Furthermore, advertisements for cosmetics and food are prohibited from indicating any disease treatment function containing medical terms or wordings that might easily cause confusion between the products promoted and pharmaceuticals, or between the products promoted and medical devices.

Cosmetics advertisements also need to conform to the requirements of other regulations and specifications, such as the *Regulations on the Supervision and Regulation of Cosmetics*, the *Cosmetics Efficacy Claims Evaluation Specification*, etc. According to the *Cosmetics Efficacy Claims Evaluation Specificatio* n, any promotion of cosmetics' efficacy must be supported by a sound scientific basis.

Health food falls under the special regulation under the *Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Health Food and Foods for Special Medical Purpose*, which stipulate that advertisements for health food must be reviewed and approved by the competent authorities before their release. Other key requirements include:

- the contents of the advertisement must conform to the contents registered or filed with those competent authorities; and
- advertisements for health food must prominently display the warning that health foods are not drugs and cannot treat any disease instead of drugs, must be marked with the official logo of health food, and must indicate the suitable and unsuitable consumers.

Internet Advertising

Advertising on medical apps may be internet advertising, which must conform to the *Interim Measures for the Administration of Internet Advertising*. For instance, the following are required: (i) internet advertisements must be identifiable as such and must be clearly marked as "advertisements" to ensure that consumers can identify them as advertisements; (ii) paid-for advertisements within search results must be clearly distinguished from natural search results; and (iii) the use of the internet to publish and send advertisements must not affect the normal use of the internet by users. Advertisements published on internet pages in the form of pop-ups or other forms must be clearly marked with a "Close" sign to ensure the ability to "Click to Close".

2.4 Marketing and Sales

Clinical Evaluation of Medical Devices

Pre-market clinical research and design of medical devices are subject to the governance of the competent authorities. The RSAMD and the *Administrative Measures for the Registration and Record-filing of Medical Devices* ("Medical Device Registration Measures") set out the legal framework regarding whether pre-market research and design of medical devices may be conducted and how they should be conducted.

According to the RSAMD and the Medical Device Registration Measures, the registration/record-filing of medical devices is subject to clinical evaluation, except for limited circumstances where (i) the medical device has a clear working mechanism, an established design and a mature production process, and the same kind of medical device has been listed on the market for years without records of material adverse events or a change of general purpose thereof; or (ii) the medical device has been proved in other ways to be safe and effective through non-clinical evaluation. The NMPA also from time to time formulates and promulgates a list of such medical devices that are exempt from clinical evaluation.

The clinical evaluation of medical devices can be carried out through clinical trials or through analysis and evaluation of the clinical literature and clinical data of the same variety of medical devices to prove their safety and effectiveness. If the existing literature and data are insufficient to evidence the safety and effectiveness of the medical devices, a clinical trial should be implemented.

In addition to the RSAMD and the Medical Device Registration Measures, an array of review standards and guidance such as Good Practice for Medical Device Clinical Trials (GCP) further specifies operational guidance and technical requirements for conducting clinical trials of medical devices. According to such regulations, conducting a clinical trial of medical devices requires consent from the ethics committee. If the product at trial is listed in the *Catalogue of Class III Medical Devices Subject to Clinical Trial Approval*, the applicant must also obtain approval from the NMPA, and such a trial can only be conducted at a Grade IIIA medical institution. In addition, if the clinical trial utilises human genetic resources and international co-operation is involved (eg, the sponsor is an enterprise invested in by a foreign enterprise or person), the applicant must first make a filing at the Ministry of Science and Technology (MOST), or even obtain prior approval from the MOST under certain conditions, eg, if the materials of human genetic resources utilised in such trial will be exported. Among other requirements under the GCP, one key requirement is to ensure that the clinical trial data is true, accurate, complete and traceable, and the sponsor must keep the basic clinical trial documents until the medical device is no longer used in the market.

Registration/Record-filing of Medical Devices

In applying for the registration/record-filing of a medical device, the applicant must submit documents regarding pre-market non-clinical research and clinical evaluation. Class I medical devices are exempt from clinical evaluation.

The medical device will be granted with an authorisation or record-filing certificate by the NMPA and its local counterparts based on its classification (please refer to **1.1 Medical Devices**). For a newly developed medical device that has not been listed in the existing *Catalogue of Medical Device Classification*, the applicant can either directly apply for its product registration as a Class III medical device, or apply to the NMPA for identification of its classification first and then apply for registration/record-filing after it has been classified. The record-filing certificate does not have an expiry date, while each medical device registration certificate is valid for five years and subject to renewal.

Distribution of Medical Devices

The distribution of medical devices is also subject to regulations that depend on their classification. The distributor of a Class II medical device must maintain a distribution record-filing receipt unless such record-filing requirement is clearly exempted; the distributor of a Class III medical device must hold a distribution licence, which will be valid for five years and subject to renewal. Distribution of Class I medical devices is not subject to special authorisation. The registrant/record-filing holder can distribute the medical devices by itself or can entrust a third-party qualified distributor to sell the medical devices.

The distribution of the medical devices must always follow the requirements under the *Implementation of the Measures for Medical Device Quality Management* (GSP) in the process of procurement, acceptance, storage, sales, transportation and after-sales services to ensure product quality. As for the record-keeping requirement under GSP, the distributor must keep all records covering the full operation process including records of procurement, acceptance, sales, storage, adverse events, inspection and training. Such records must be kept for two years after the life span of the medical device. For a medical device without a life span, the aforesaid records must be kept for at least five years. For an implantable medical device, the aforesaid records must be kept permanently.

Online sales of medical devices are generally permitted with a prerequisite filing. In order to publicise information about a medical device on a website for online sales, the online distributor (in terms of a self-operated platform) or the platform provider (in terms of a third-party sales platform) must obtain an Internet Drug Information Service Qualification Certificate. The online distributor must also obtain other applicable qualifications and requirements necessary for operating a website for such purposes.

Special Requirements for Healthcare Products

For cosmetics, in the pre-market stage, safety assessments must be conducted in accordance with technical guidelines, such as the Technical Guidelines for Cosmetic Safety Assessment (2021), to assess the potential safety risks of each raw material and/or hazardous substance in the cosmetics and form a product safety assessment report. The assessment report is one of the mandatory submissions when registering/record-filing a cosmetic product.

In terms of food, pre-market requirements mainly involve product registration/filing of health food, a marketing business licence and a safety assessment.

Firstly, health food is under special regulation requiring its registration or record-filing. To be specific:

- (i) health food using raw materials not listed in the *Administrative Measures for the Catalogue of Ingredients* or (ii) health food imported for the first time must be registered with the competent authority before their production and import; and
- health food using raw materials listed in the *Administrative Measures for the Catalogue of Ingredients* and health food consisting of supplementary vitamins, minerals and other nutrients which are imported for the first time must be record-filed with the competent authority before their production and import.

Secondly, food manufacturers must inspect the quality of food before its listing on the market and implement an inspection control system to ensure food food safety.

Special Requirements for Medical Apps

As discussed in **1.3 New Products/Technologies and Digital Health**, a medical app could be a kind of medical device software. According to the Appendix, pre-market requirements for standalone software are mainly the design development requirements, which include the specific requirements for activities such as quality assurance, software risk management, software configuration management, software version control, software traceability analysis, software development planning, software demand analysis, software coding, software verification, software validation, user testing, software updates and software defect management, etc.

With respect to sales and after-sales services, the Appendix requires that the deployment and discontinuation of the software shall be documented. The deployment of software includes activities such as delivery, installation, setting up, configuration, user training, etc, which must be documented or recorded. As for discontinuation of the software, the following situations and activities shall be kept in records: subsequent user services after the discontinuation, data migration, protection of patient data and privacy, user notification, etc.

Furthermore, regarding adverse events, the Appendix also stipulates that enterprises shall set up data analysis control procedures, which shall cover the requirements of software defects and cybersecurity incidents. Emergency responses to cybersecurity incidents must be documented, which include activities such as user notification, recall, cybersecurity incident risk management, etc.

2.5 Internationalisation

Potential Restriction on Exporting Medical Devices or Related Technologies

An authorisation administration mechanism has been implemented for the export of dual-use biological goods and related equipment and technologies listed in the *Catalogue for the Administration of Import and Export Authorisation for Dual-Use Items and Technologies* ("Control List"). The dual-use biological substances and related equipment and technologies listed in the Control List may only be exported with prior authorisation. If a medical device or the technologies related to such medical device fall under the Control List, the export application will be examined and approved by the competent provincial Commerce Bureau.

Also, if the related technologies of medical devices fall under the *Catalogue of Technologies Prohibited from Export*, such medical devices will be prohibited from exportation. If the related technologies of medical devices fall under the *Catalogue of Technologies Restricted from Export*, prior authorisation is required for the export of such medical device.

If medical apps involve the activities of exporting personal information and human genetic resources information, the relevant export restrictions should also be observed and the approval of the competent authority should be obtained.

Imported Medical Devices

Overseas inspection of the manufacturing site

A product registration/record-filing with the NMPA and its local counterparts must also be obtained for an imported medical device in order for it to be marketed in the PRC. If a medical device marketed in the PRC or proposed to be marketed in the PRC is developed or manufactured overseas, the NMPA is entitled to conduct an overseas inspection to ensure the authenticity, reliability and compliance of the process relating to the overseas development and production of such medical device.

Imported medical devices to be manufactured within the PRC

Under the PRC legal regime, imported medical devices and locally manufactured medical devices are registered according to different procedures. If an imported medical device is to be manufactured within the PRC, it must go through the registration procedure and obtain another registration certificate. According to the *Announcement of the NMPA on Matters Concerning the Production of Imported Medical Device Products by Enterprises within the PRC* promulgated in 2020, an imported Class II or III medical device can be manufactured within the PRC in an easier way if the manufacturer of the medical device to be manufactured within the PRC is invested in by the overseas registrant of the medical device. On the premise that the design of the medical device is not changed, that the quality system is basically consistent and that the safety and effectiveness of the medical device are not significantly changed, the original registration application materials submitted for imported medical devices will be recognised by the NMPA in applying for the registration of the locally manufactured medical device.

Also, cross-border entrustment of manufacturing the imported medical device is open within a limited range. According to the *Implementation Plan for Supporting Medical Device Registrants of Hong Kong and Macao in Manufacturing Medical Devices in Nine Mainland Cities in the Greater Bay Area*, after obtaining the imported medical device registration certificate issued by the NMPA, the Hong Kong and Macao medical device registrants can entrust a qualified manufacturer in nine mainland cities of the Greater Bay Area (namely, Guangzhou, Shenzhen, Zhuhai, Foshan, Huizhou, Dongguan, Zhongshan, Jiangmen and Zhaoqing) to manufacture such medical devices.

Healthcare Products

As products that may have an impact on health, cosmetics and food are highly regulated products whose importation as well as exportation, in addition to the general regulations, should also comply with special regulations, namely:

- the import and export of cosmetics need to comply with the *Measures for the Inspection, Quarantine, Supervision and Administration of Import and Export Cosmetics*; and
- food should comply with the *Administrative Measures for the Safety of Imported and Exported Food Products*.

Valued-added Telecommunications Services

If a medical app involves value-added telecommunications services, the foreign equity of the company is restricted to no more than 50% in accordance with the *Special Administration Measures (Negative List) for Foreign Investment Access (Edition 2021)*.

2.6 Post-marketing Obligations, Including Corrective Actions and Recalls

Post-marketing Obligations on Medical Devices

According to the RSAMD and other medical device-related laws and regulations, the MAH of a medical device is responsible for post-marketing obligations, including:

- establishing and maintaining a quality management system – the MAH is responsible for the quality management of the whole life cycle of the medical device and shall meet all the record-keeping requirements in the process of its development, manufacturing and distribution. Please refer to **2.1 Design and Manufacture** and **2.4 Marketing and Sales**. The MAH shall conduct regular self-inspections of the operation of the quality management system and submit reports of such inspections as required;
- setting up and implementing the post-marketing research and risk management and control plan – as required by law, the MAH shall take the initiative to carry out post-marketing research on medical devices to further confirm the safety, effectiveness and quality controllability of medical devices and strengthen the continuous post-marketing management of medical devices;
- monitoring and re-evaluating medical device adverse events (AEs) – according to the *Administrative Measures for Medical Device-Related Adverse Event Monitoring and Re-evaluation*, the MAH shall establish a medical device-related AE monitoring system and fulfil the following main obligations:
  (a) being equipped with organs and personnel for medical device-related AE monitoring work; and
  (b) proactively collecting and truthfully reporting to the monitoring institutions any medical device-related AEs in a timely manner;
- investigating, analysing and evaluating any medical device-related AEs that have occurred, taking measures to control risks and releasing risk information in a timely manner;
- conducting continuous research into the post-marketing safety of medical devices and preparing risk assessment reports periodically as required;
- voluntarily carrying out medical device re-evaluation;
- co-operating with the competent authorities regarding the investigation of AEs; and
- establishing a tracking and recall mechanism – detailed regulations on tracking and recall mechanisms have been stipulated under the *Administrative Measures for Medical Device Recalls*. According to such regulations, if the MAH finds out that medical devices do not meet the mandatory standards or the registered or filed technical requirements or that there are other defects, the MAH shall immediately stop their production, notify the relevant distributors, users and patients to stop their distribution and use, recall the medical devices that have been sold on the market, take remedial, destruction and other measures, record and release the relevant information and report the relevant circumstances to the competent authorities. If any manufacturer or distributor finds out the above circumstances, such manufacturer or distributor shall stop the manufacturing or distribution of such medical devices and notify the MAH accordingly.

Healthcare Products

Cosmetics and food products are highly regulated in respect of post-marketing. The main regulatory system is the product recall system.

When the registrants, filers, manufacturers or business operators of cosmetic products find

any defects or other matters that may be harmful to human health, they should cease their manufacture and recall any products that have been marketed.

When the manufacturers of food products find that products fail to meet standards of food safety or find any evidence indicating that products may be harmful to human health, those manufacturers must immediately cease their manufacture and recall any products that have been marketed. If a business operator finds the above-mentioned reason to recall, they also need to notify the manufacturers to cease the manufacturing.

3. REGULATOR ENGAGEMENT AND ENFORCEMENT

3.1 Regulatory Authorities

Regulatory Authorities in Respect of Medical Devices

SAMR

The State Administration for Market Regulation (SAMR) is the authority on the national level for market supervision, administration and law enforcement relating to medical devices, particularly from the perspectives of product quality safety, issuance of business registrations and certifications of enterprises, and anti-monopoly and unfair competition including commercial bribery. The SAMR at the provincial and city levels is also in charge of the law enforcement relating to medical devices including advertising activities and operational compliance issues such as commercial bribery.

NMPA

The NMPA, as a national bureau operating under the supervision of the SAMR, regulates the registration, post-marketing risk management, administration of safety and quality, formulation of standards, and supervision and inspection of medical devices. The NMPA authorises its local counterparts to administer the issuance of filing receipts of certain product admission and manufacturing and distribution permits.

In addition, the NMPA's affiliated organisation, the CMDE, is specifically responsible for the technical evaluation of medical devices.

Other regulatory authorities

Other regulatory authorities may also be involved in the administration of medical devices if certain activities or matters fall under their powers, eg, if human genetic resources are utilised during the clinical trials of a medical device, this may be subject to the administration of the MOST; please refer to **2.4 Marketing and Sales**.

Healthcare Products

Cosmetics

The competent authorities that oversee the regulatory compliance of cosmetics are the Department of Cosmetics Supervision and Administration under the NMPA, and the SAMR.

- The NMPA governs cosmetics matters ranging from general safety and quality supervision and management, standard management, cosmetic registration/recordation, to post-market risk management and supervision as well as inspection.
- The SAMR supervises and manages the business operation of cosmetics, investigates, and punishes violations of market supervision and management regulations, such as illegal advertisements, unfair competition and infringement of consumer rights and interests. Such work is enforced day-to-day by the provincial, municipal and district departments of the AMR.

Food
The authorities governing food include the National Health Commission (NHC) and the SAMR.

The SAMR supervises and manages food production and circulation, and catering service activities. Day-to-day law enforcement is performed by the provincial, municipal and district departments of the AMR.

The NHC is one cabinet-level executive department of the State Council, which is responsible for formulating food safety standards, conducting food safety risk monitoring and risk assessment, and has the duty of stipulating the qualification criteria for food inspection agencies and inspection specifications.

3.2 Regulatory Enforcement Mechanisms
Please see **3.1 Regulatory Authorities**.

4. LIABILITY

4.1 Product Safety Offences
The PRC legal regime for product liability includes civil penalties, administrative penalties and criminal penalties.

Civil Penalties
In the event of product defects which cause damage to others or threaten the personal safety or the property security of others, the manufacturer or distributor of the products will bear civil penalties such as cessation of infringement, removal of obstacles, elimination of danger, and the payment of compensation and punitive damages.

Administrative Penalties
If a medical device company commits any illegal acts (eg, violating the RSAMD or other applicable laws and regulations), it will be subject to administrative penalties/punishment by the competent authorities. In accordance with different circumstances, the administrative penalties for medical device companies include giving a warning, ordering the company to make corrections within a time limit, confiscating any illegal gains, imposing fines, revoking administrative permission, ordering the company to suspend production or operation of medical devices, and rejecting applications for medical device permits. For personnel with related responsibility, the administrative penalties include imposing fines and administrative sanctions, and prohibiting such personnel from engaging in the production or operation of medical devices for a certain period or for life.

The NMPA and local Medical Product Administrations ("local MPAs") have published typical cases or examples of the above penalties from time to time in recent years.

Criminal Penalties
If the illegal acts of a medical device company involve criminal offences, the personnel with related responsibility will be subject to criminal penalties such as criminal detention, fines, confiscation of property, and fixed-term imprisonment or life imprisonment.

4.2 Product Liability
The PRC legal regime for product liability claims can generally be divided into two main categories: contractual liability and tort liability.

Contractual Liability
The general principle of contractual liability is provided in the Civil Code, which is that where any party fails to perform its obligation under a contract or its performance fails to satisfy the terms of the contract, it shall bear the liability for breach of contract such as taking remedial measures or compensating for losses.

Tort Liability

Tort liability is also provided in the Civil Code, which refers to the circumstance that whoever is at fault in infringing upon other parties' civil rights and interests and causing damage thereto shall bear tort liability. Therefore, generally in tort liability claims, the plaintiff needs to prove that the defendant is at fault, such as having committed intentional or negligent acts. However, the above fault principle does not apply to product liability claims. According to the Civil Code, for product defects that have caused damage to others, the manufacturer or distributor shall bear tort liability. In other words, in product liability claims, the plaintiff only needs to prove the following: (i) the product has defects, (ii) damage occurred to the plaintiff, and (iii) a causal relationship exists between the product defects and the damage, while it is not required to prove the intent or negligence of the defendant (the manufacturer or the distributor).

When contractual liability and tort liability occur together under the same legal facts, as per the Civil Code, where one party breaches an agreement and causes damage to the other party's personal or property rights and interests, the damaged party or the plaintiff has the right to request the defendant to assume either contractual liability or tort liability.

4.3 Judicial Requirements

Civil Action

For civil lawsuits concerning personal injury to others or damage to others' property due to torts or product quality issues, the People's Court at the location of the defendant's domicile, or at the place where the product is manufactured or sold or where the tort was committed, has jurisdiction. Depending on the impact of the case, the court level may be the basic, intermediate or high People's Court or Supreme People's Court.

Criminal Action

In general, the People's Court in the place where a crime is alleged to have been committed has jurisdiction. However, if it is more appropriate for the trial to be held at the People's Court of the defendant's place of residence, such court may have jurisdiction over the case. Depending on the severity of the alleged crime and the possible punishment the defendant may be sentenced to, the court with jurisdiction may be a basic People's Court, an intermediate People's Court, a high People's Court or the Supreme People's Court.

Public Interest Action

Civil public interest litigation (see **4.6 Class Actions, Representative Actions or Co-ordinated Proceedings**) cases fall under the jurisdiction of the intermediate People's Court at the place where the tort was allegedly committed or where the defendant is domiciled.

Administrative Supervision

The local MPA (see **3.1 Regulatory Authorities**) above the county level is responsible for the supervision and management of medical devices in its administrative region. The local AMR (see **3.1 Regulatory Authorities**) above the county level is responsible for the supervision of product quality within its administrative regions.

Civil public interest litigation (see **4.6 Class Actions, Representative Actions or Co-ordinated Proceedings**) cases fall under the jurisdiction of the intermediate People's Court at the place where the tort was allegedly committed or where the defendant is domiciled.

4.4 Costs

When the consumers or the injured parties prevail in product liability cases, in addition to compensating the loss suffered by the prevailing party, the losing party must pay the litigation fee

and/or property preservation fee to the court, and sometimes even must reimburse part of the costs paid by the prevailing party, including but not limited to attorneys' fees, application fees for property preservation, translation fees, notary fees, appraisal and assessment fees, etc.

4.5 Product-Related Contentious Matters

AEs

In the case of AEs pertaining to medical devices that cause sudden or mass severe injury or death, provincial Medical Products Administrations and/or the NMPA shall, in conjunction with the Health Commission at the same level, organise investigations into such AEs in a timely manner and handle such AEs in accordance with the *Regulation on the Supervision and Administration of Medical Devices.*

Product-related Contentious Matters

Product-related contentious matters may involve forensic identification such as medico-legal identification, physical evidence identification and audio-visual materials identification, to identify and determine the specialised issues or obtain expert opinions on the contentious matters in accordance with the General Rules on Procedures for Forensic Identification and relevant regulations.

With respect to product-related contentious matters between consumers and business operators, consumers may lodge a complaint with the relevant administrative authorities in accordance with the *Law of the PRC on the Protection of Rights and Interests of Consumers* and *Provisional Measures for the Handling of Complaints and Whistle-blowing Report on Market Regulation*.

Unfair Competition

With respect to unfair competition and other violations by business operators, any organisation or individual has the right to report alleged unfair competition to the regulatory authorities based on the *Law of the PRC Against Unfair Competition* and report other suspected violations based on the *Provisional Measures for the Handling of Complaints and Whistle-blowing Report on Market Regulation*.

With respect to product-related contentious matters between consumers and business operators, consumers may lodge a complaint with the relevant administrative authorities in accordance with the *Law of the PRC on the Protection of Rights and Interests of Consumers* and *Provisional Measures for the Handling of Complaints and Whistle-blowing Report on Market Regulation*.

4.6 Class Actions, Representative Actions or Co-ordinated Proceedings

Joint Action

In China, several conditions need to be met to initiate a joint action:

- the plaintiff (or defendant) must comprise more than two persons;
- the subject matter of the lawsuit must be common, or the subject matters must be of the same type;
- the People's Court must deem that the lawsuit is suitable for a joint trial; and
- the parties must agree to adopt the proceedings of a joint trial.

Therefore, if a medical device-related case meets the above circumstances, it will proceed as a joint action. If persons (together as one party) to a joint action have common rights and obligations with respect to the subject matter of the litigation, and if the action of one of them is recognised by the other(s), such action would become effective for the other(s).

Representative Action

There has been no medical device-related representative action in China until now. However, several important documents issued by the Chinese government have clearly stated that it is necessary to explore the establishment of a consumer representative action system.

Public Interest Action

In China, state organs and relevant organisations may bring lawsuits to the People's Court against acts that harm the public interest of society, such as pollution of the environment and infringement of the legal rights and interests of consumers. In addition, if the People's Procuratorate finds out that there is a tort of the legal rights and interests of consumers in the field of food and medical product safety, it can bring a lawsuit to the People's Court. In practice, there have been some public interest action cases against pharmaceutical producers in different places in China.

4.7 ADR Mechanisms

Civil disputes arising from product quality may be settled through consultation or mediation or submitted to an arbitration agency as agreed by the parties according to the *Product Quality Law of the PRC*.

With respect to consumer complaints regarding product quality and other product or service issues, the China Consumers Association and local Consumers Association shall receive such consumer complaints and conduct investigations into those complaints and provide mediation support according to the *PRC Law on the Protection of Rights and Interests of Consumers*.

To promote compliance and the law-abiding operation of enterprises, the Supreme People's Procuratorate issued the Plan on Carrying out the Pilot Programme of Corporate Compliance Reform, which states that when making a decision not to arrest, not to prosecute or to propose a lighter sentence in criminal cases involving enterprises, the procuratorates shall supervise and urge the enterprises involved to make compliance commitments and to actively implement such commitments. It should be noted that this system of non-prosecution can only be applied to minor cases of corporate criminal offences (including offences committed by individuals such as business operators). In practice, the types of criminal offences include crimes of major liability for accidents, crimes relating to environmental pollution, commercial bribery and crimes relating to taxation, etc.

4.8 Interrelation Between Liability Mechanisms

Case Referral Between Judiciary Authorities and Administrative Authorities

In accordance with the *Administrative Penalty Law of the PRC*, where an illegal act is suspected of constituting a crime, the administrative authority shall refer the case to the competent judiciary authority to investigate the issues of criminal liability in a timely manner. Where a case is exempted from criminal liability but administrative penalties may be imposed, the judiciary authority shall refer the case promptly to the competent administrative authority.

Judicial Review of the Administrative Act

According to the *Administrative Procedure Law of the PRC*, where a specific administrative act has one of the following circumstances, the court may overturn or partially overturn the administrative act or require the administrative authority to make a new administrative act: (i) inadequacy of essential evidence, (ii) erroneous application of laws and regulations, (iii) violation of legal procedures, (iv) exceeding authority, (v) abuse of power, or (vi) obvious unfairness. Furthermore, if an administrative sanction is obviously unfair, or there is a definite error regarding the amount of money in a specific administrative

act, such administrative sanction or administrative act may be amended by judicial judgment.

Supervision by Prosecuting Authorities

According to the Opinions of the Central Committee of the Communist Party of the PRC on strengthening the legal supervision of prosecuting authorities in the new era (the "Opinions"), the Opinions emphasise the legal supervision function of prosecuting authorities and require a system to be established for judicial information sharing, case information reporting and case referral among prosecuting authorities, administrative authorities, judiciary authorities and public security organs.

Cross-Sectoral and Cross-Regional Co-operation on Drug and Medical Device Supervision

Based on the Notice issued by NMPA, local MPAs shall co-operate closely with local public security organs and local AMRs for drug and medical device supervision. If the local MPA finds any illegal acts such as monopoly and false advertising during an inspection, it shall timely refer the case to the competent local AMR to further investigate the above issues and impose punishment. If the local MPA finds that any illegal acts are suspected of constituting crimes, it shall timely refer the case to the competent local public security organ to investigate the issues of criminal liability. With respect to cross-regional cases, local authorities shall co-operate closely to investigate and punish the illegal acts.

5. POLICY AND LEGISLATIVE REFORM

5.1 Policy Development

Healthcare Products

In 2020, the newly revised *Regulations on the Supervision and Regulation of Cosmetics* established a new supervision system applying to cosmetics. Since then, a number of supporting regulations for cosmetics have been revised. The tendency mentioned in the policy for the next step is, firstly, to update the technical specifications of cosmetics to reflect the revisions to the regulations, and then to implement and enforce those new cosmetics regulations strictly.

Food safety is the spotlight of the policy. The Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035 sets out the goal to improve and advance the regulatory system on food safety, and explore a system of punitive damages in civil public interest litigation on food safety.

Software

In the 14th Five-Year Plan Software and Information Technology Service Industry Development Plan, issued by the Ministry of Industry and Information Technology, it is stated that in the respect of the use of big data, the development of technologically advanced software products is encouraged in key areas including medical care. We anticipate that it will help promote the development of medical apps and possibly push the relevant legislation to adapt to the development of the industry.

5.2 Legislative Reform

Medical Devices

Since the updated RSAMD came into effect in 2021, many supporting regulations have been promulgated and implemented, including management measures related to medical device registration, production, operation and clinical trials.

The SAMR has announced its legislation plan to continually improve the regulatory system and to review the revision of the *Product Quality Law* within this year. In addition, it intends to initiate and promote legislative amendments to the rules on monitoring and re-evaluation of medical

device AEs as well as the rules on product anti-counterfeiting.

Environmental Protection

In terms of environmental protection, the Ministry of Ecology and Environment stated that during the 14th Five-Year Plan period (2021–2025) it would further strengthen ecological environment legislation and promote the formulation or revision of laws and regulations in key areas such as electromagnetic radiation pollution prevention and control. Additionally, it would improve the legal system of responsibility for violations of the regulatory regime of the ecological environment. For instance, it would build a legal liability system with administrative liability as the mainstay, with criminal liability and civil liability that may also apply, and continually strengthen the main responsibility of enterprises and institutions for ecological and environmental protection.

Healthcare Products

Since 2020, several updated regulations on cosmetics have come into effect, following in the footsteps of the *Regulations on the Supervision and Regulation of Cosmetics*. More new supporting regulations and regulatory documents will take effect or be promulgated; for example, the *Administrative Measures for the Monitoring of Adverse Reactions of Cosmetics* will take effect from 1 October 2022, and the *Major Points of Inspection and Judging Principles of Cosmetic Production Quality Management Standard* are currently being drafted. Those regulations will jointly build a comprehensive regulatory framework for cosmetics in the near future.

Concerning food, the competent authorities intend to upgrade the laws, regulations and standards on food safety. The *2022 Work Plan for the Formulation of Regulations of the SAMR* indicates that the SAMR proposes to formulate/revise the regulations for the administration of food business licences and record-filing and to formulate/revise the measures for the supervision and administration of the quality and safety of food-related products.

5.3 Impact of COVID-19

There have been flexibilities in registration and manufacturing certification during COVID-19. Many Chinese provinces and cities have introduced special regulations to facilitate the application for manufacturing permits for medical devices. For example, registration and manufacturing of medical masks and medical protective clothing are no longer subject to approval. The NMPA has also approved certain INDs and NDAs (conditional approval) relating to COVID-19 vaccines and therapeutic drugs through special approval procedures, and detection reagents have also been approved through the emergency approval process. In the future, China will continue to promote emergency approval of products relating to COVID-19 epidemic prevention and control.

At the same time, the quality and safety of products remain the focus of attention. During the epidemic, the NMPA has repeatedly inspected the production of COVID-19 vaccines to ensure their quality and safety. And some special regulations were issued to severely crack down on the illegal manufacture and distribution of counterfeit and inferior pharmaceuticals, medical devices and hygienic materials, especially for pharmaceuticals and medical devices used for the treatment and prevention of COVID-19, such as protective clothing, medical masks, testing reagents, ventilators, etc.

Global Law Office (GLO) dates back to the establishment of China's Legal Consultant Office of the Council for the Promotion of International Trade in 1979. After years of persistent endeavours and development, GLO has become one of the largest and leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. Its life sciences and healthcare (L&H) practice group is one of the earliest L&H teams in China, having provided "one-stop" legal services for every area of the L&H industry, including M&A, investment and funding, licence in and out, daily operation, IP protection, and advice on compliance including internal and government investigations as well as anti-bribery matters and dispute settlement. Under a changing regulatory environment, GLO's L&H team has the perfect combination of international experience and local know-how to support various innovation or pilot projects, including digital healthcare, MAH/cMAH trial cases, etc. GLO's L&H team deeply participates in the formulation of local codes of conduct and benchmark policies/rules. GLO's L&H team also has close cooperation with associations, including CPIA, RDPAC, ACCP and so on.

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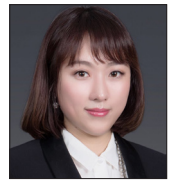

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