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Healthcare: Medical Devices 2024

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China: Law and Practice

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Global Law Office

CHINA

Law and Practice

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Contents

Global Law Office dates back to the establishment of China's Legal Consultant Office of the Council for the Promotion of International Trade in 1979. 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 and pilot projects, including digital healthcare and MAH/CMAH trial cases. GLO's L&H team deeply participates in the formulation of local codes of conduct and benchmark policies/rules.

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1. Applicable Product Safety Regulatory Regimes

1.1 Medical Devices

Product Safety Regulatory Regime for Medical Devices

Classification of medical devices

Under the PRC's 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 product, 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 acting as auxiliary functions. "Medical instrument" is not a legally defined term under the PRC's 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 therefore are subject to registration administration under the supervision of the NMPA.

The NMPA has issued the Rules for Medical Device Classification, the Catalogue of Medical Device Classification, the Catalogue of Class I Medical Device Products, the Rules for In Vitro Diagnostic Reagents Classification and the Catalogue of In Vitro Diagnostic Reagents 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

See **1.4 Technologies and Digital Health**.

Product Safety Regulatory Regime for Personal Protective Equipment (PPE)

PPE 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 the State 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, such as medical protective respirators and medical protective clothing, 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

Cosmetics are 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.
- Ordinary cosmetics (cosmetics other than special cosmetics) need only to 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 (including GMOs) 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. The Food Safety Law regulates the production, distribution, safety, labels, inspection, and import and export of food products, and there are many specific regulations regulating different kinds of food, such as the Administrative Measures for Registration and Record-filing of Health Food, and the Regulations on Administration of Agricultural Genetically Modified Organisms Safety. Thus, nutrition supplements must follow the Food Safety Law and 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 Medicines

"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 (DAL), which governs various drug-related activities, including their development, registration, manufacturing, and distribution.

Clinical trials of pharmaceuticals are regulated by laws and an array of guidance and technical review standards. Specifically, the DAL, the Administrative Measures for Drug Registration (2020 Revision), and the Good Clinical Practice (GCP) outline the framework for administration on clinical trials of pharmaceuticals, and specify the detailed obligations of the parties involved, operational procedures, and technical requirements.

Details on the regulation of pharmaceuticals and relevant clinical trials can be viewed in the **Chinese Law and Practice** chapter in the 2024 Chambers Life Sciences Global Practice Guide.

Blood Products

Under the PRC's legal regime, blood products refer to, in particular, various human plasma protein products, which are governed as pharmaceuticals, and further as biological medicinal products. As a special category of medicinal products, in addition to the regulations generally applicable to drugs, blood products are also subject to the Regulations on the Administration of Blood Products and other special regulatory requirements. For instance, the source plasma for the production of blood products shall only be obtained from a qualified supplier, blood products are generally subject to batch release administration prior to marketing, and blood products shall not be contracted for manufacture or sold online. China is accelerating the informatisation construction of the blood product production and inspection processes. The NMPA has issued the Smart Supervision Three-Year Action Plan for Blood Product Production (2024–2026), aiming to essentially achieve informatised management in blood product production enterprises by the end of 2026.

Psychedelics

"Psychedelics" is not a defined legal term under the PRC laws. Generally, psychedelics refer to materials that stimulate the central nervous system and cause false sensations, changes in temperament, increased pulse rate, increased blood pressure and body temperature, pupil dilation, and other physical and psychological changes. Certain psychedelics, if used properly, may function as a psychotropic substance. If such psychedelics further fall within the Catalogue of Psychotropic Substances, it is eligible to be

applied under the administration of NMPA and registered as a drug subject to regulation. The Catalogue of Psychotropic Substances is established, updated, and published by the NMPA in conjunction with the Ministry of Public Security and the National Health Commission. Under the PRC laws, psychotropic substances are categorised and regulated based on their risk level, from high to low, into Class I and Class II. The Class I psychotropic substances, which are classified as having the highest risk level, must be manufactured and sold under strict control. In addition to the regulations generally applicable to drugs, psychotropic substances are also subject to the Regulations on the Administration of Narcotic Drugs and Psychotropic Substances (2016 Revision) and other special regulatory requirements. For instance, the R&D and manufacturing of psychotropic substances are subject to special approval and psychotropic substances shall neither be contracted for manufacture nor sold online.

Cannabidiol (CBD)

CBD is an active ingredient of cannabis that 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. In this sense, medicinal products containing CBD are subject to regulations generally applicable to medicinal products.

1.4 Technologies and Digital Health

Certain medical apps, tele-medicine 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 **1.1 Medical 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.

Tele-medicine

A tele-medicine information system is used for tele-medicine services. According to Good Practices for Tele-medicine Services (for Trial Implementation), the tele-medicine information system shall ensure that images, sounds, texts and other medical information required in the tele-medicine service can be transmitted safely and in time, and ensure that the images are clear and that the data is accurate. The tele-medicine information system must also conform to the Technical Guidelines for Construction of the Tele-medicine Information System and meet the requirements of clinical diagnosis.

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

Stem Cells

Stem cells are self-renewing, highly proliferative cells that can further differentiate into various tissue cells. Chinese regulation of stem cell products has gone through a transition from treating them as drugs at the beginning, to treating them as a third type of medical technology, and currently to treating them as drugs. In addition to the regulations generally applicable to drugs, human stem cells are a prohibited field for foreign investment, but Beijing and Shanghai are actively exploring the gradual liberalisation of access restrictions. For clinical research on stem cells, a dual filing of "research organisation" and "research project" is required, as well as an ethical review, and no advertisements for clinical research on stem cells are allowed to be published.

1.5 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 products.

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, applicants should apply for its registration as a drug if it mainly acts as a drug, and as a medical device if it mainly acts as a medical device. According to the Rules for Medical Device Classification, if a combination product mainly acts as a medical device, it shall be managed as class III medical devices. 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. IVD reagents are categorised by risk level from low to high into Class I, Class II, and Class III. IVD reagents of Class I are subject to record-filing administration. IVD reagents of Class II and Class III are subject to registration administration.

PPE and Medicines

PPE 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 for 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 non-conforming products, monitoring, analysis and remediation of adverse events, and other specific requirements for certain products.

- 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, and risk management and control measures. Design and development outputs must meet the input

requirements, including the relevant information needed for purchase, manufacture and services, and product technical requirements.
- The manufacturer must keep legible and complete records that ensure the traceability of activities such as the manufacture and quality control of the products.
- Unless otherwise specified by the applicable laws or regulations, all the records must be retained for a period at least equivalent to the lifespan 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 new Measures for the Supervision and Administration of Medical Device Manufacture promulgated in 2022 deleted the chapter of "Management of Entrusted Manufacturing", and integrated the relevant requirements into the quality management system for unified management.

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 materials and products, 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, and storage and packaging, as well as inspection and control over finished products, transportation, and delivery.

Requirements for Manufacturing Medicines

Generally, the manufacture of medicines must comply with the DAL, the Measures for the Supervision and Administration of Drug Manufacture, and Good Manufacturing Practice for Medicines, among other regulations and guidelines in the PRC. Under such legal framework, the prerequisites for manufacturing medicines include obtaining drug manufacturing licenc-

es and having pharmaceutical manufacturing plants. More stringent requirements further apply to special medicines, for instance, the manufacture of blood products, narcotic drugs, and psychotropic substances cannot be entrusted to another manufacturer other than the MAH. For more detailed requirements on the manufacture of medicines, refer to the **Chinese Law and Practice** chapter in the 2024 Chambers Life Sciences Global Practice Guide.

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 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:

- 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
- with respect to design specifications, the Appendix requires that the software design specifications and relevant review records are formulated, approved, and updated in good time.

Special Rules and Standards for Wearables

For wearables that meet the definition of medical devices and are regulated as medical devices, the NMPA has issued several technical guidelines and product registration guidance for certain medical device wearables, such as pulse oximeters, wearable mobile medical devices (eg, smart glasses, smart watches, etc).

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, and GB/T41265.

Furthermore, wearables using GSM/GPRS, CDMA, CDMA1X, CDMA2000, TD-SCDMA, WCDMA, and TDLTE standards must obtain China Compulsory Certification (CCC).

2.2 Corporate Social Responsibility, the Environment and Sustainability

There is a national trend towards strengthening the legislation on corporate social responsibility. The new Company Law, which came into force in July 2024, emphasises that companies should take full account of the interests of interested party such as the company's employees and consumers, as well as the public interests of society such as ecological and environmental protection, and assume social responsibility. The Shanghai Stock Exchange and the Shenzhen Stock Exchange also require listed companies to publish ESG reports disclosing the information on environment and social responsibilities. 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 the Pesticide Industry (Second Draft for Comment – 2022), the Water Pollutant Discharge Standard for the Cosmetics Industry (Draft for Comment – 2010), and the Cleaner Production Standard for the Daily-use Chemical Industry (Cosmetics – Draft for Comment – 2009).

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 Purposes (effective in 2020, 2023 SAMR initiated revision with a draft for comment) 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 targets 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 introduce or recommend 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; eg, 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 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 instructions carefully or purchase and use the product under the guidance of a healthcare practitioner." Where there are contra-indications and precautions in the registration certificate of the medical device, the advertisement must also prominently display these words: "Please refer to the product instructions for contra-indications 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", or "awards", or any warranties such as "refund upon ineffectiveness" or "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, and the Cosmetics Efficacy Claims Evaluation Specification. According to the Cosmetics Efficacy Claims Evaluation Specification, 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 that:

- 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.

Medicines

The commercial advertisements of medicines are subject to regulatory frameworks similar to those of medical devices. Under such laws and regulations, the advertisements of medicines cannot be published until examined and pre-approved by the competent authorities under the SAMR, and the advertisement must clearly indicate such approval number. Advertisements of certain medicines are prohibited, such as narcotic drugs and psychotropic substances. The content of medicine advertisements must conform with the drug instructions approved by the NMPA, along with other restrictions.

Internet Advertising

Advertising on medical apps may be internet advertising, which must conform to the Measures for the Administration of Internet Advertising. For instance, the following are required:

- internet advertisements must be identifiable as such and must be clearly marked as "advertisements" to ensure that consumers can identify them as advertisements;
- paid-for advertisements within search results must be clearly distinguished from natural search results; and
- 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, generally the applicant must conduct clinical evaluation, either through pre-market non-clinical research or clinical trials.

The medical device will be granted with an authorisation or record-filing certificate by the NMPA and its local counterparts based on its classification (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, inspec-

tion, 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:

- health food using raw materials not listed in the Administrative Measures for the Catalogue of Ingredients, and health food imported for the first time, must be registered with the competent authority before 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 being imported for the first time must be record-filed with the competent authority before 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 safety.

Registration and Distribution of Medicines

Similar to the regulation on medical devices, all medicines are subject to registration with the NMPA before their launch on the market. Generally, each drug product shall go through three phases of clinical trials for registration purposes, and generate sufficient data on its safety, validity, and efficacy before the MAH submits the new drug application for registration. For each clinical trial for registration purposes, the sponsor shall file with the NMPA and obtain a permit to conduct the trial.

In distributing a medicine, the distributor must maintain a drug distribution licence, with an exception that the MAH may sell its own drugs as a wholesaler without obtaining a drug distribution licence. The distribution of medicines must always follow the requirements under the Good Supply Practice for Pharmaceutical Products. Further, the Administrative Measures for the Supervision of Online Medicine Sales, which

came into effect in December 2022, alleviate the restriction on online sales of prescriptive drugs, and, for the first time, provide the systematic regulations for online sales of medicine. According to this regulation, only a MAH or an enterprise with a drug distribution licence is eligible to conduct online sales of drugs. The operator shall also follow the requirements of good supply practice, for instance, drug traceability, quality control, and reporting on adverse effects. For online sales of prescriptive drugs, the operator has an obligation to check the prescription before providing sales service, details on the registration and distribution of medicines can be viewed in the **Chinese Law and Practice** chapter in the 2024 Chambers Life Sciences Global Practice Guide.

Special Requirements for Medical Apps

As discussed in **1.4 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.

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, and user training, 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; and
- user notification.

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, and cybersecurity incident risk management.

2.5 Internationalisation

Potential Restriction on Exporting Medical Devices or Related Technologies

Under the Export Control Law, 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 (in order to support the implementation of the new version of the Regulation on the Supervision and Administration of Cosmetics in 2021, the

Customs has issued a draft for comments in May 2024 to start the revision work); and
- food should comply with the Administrative Measures for the Safety of Imported and Exported Food Products.

Stem Cell Technology

Although foreign investment is prohibited in the field of development and application of human stem cell or related technology, Beijing and Shanghai are actively exploring the gradual liberalisation of access restrictions.

Value-Added Telecommunications Services

If a medical app involves value-added telecommunications services, generally 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 (2021 Edition). However, foreign equity ratio restrictions on related businesses have been removed on a pilot basis in specific regions in Beijing, Shanghai, Hainan and Shenzhen.

2.6 Post-marketing Obligations, Including Corrective Actions and Recalls

Post-marketing Obligations Regarding 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 the following.

- 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. 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.
- 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.

Post-marketing Obligations Regarding Medicines

The post-marketing regulation of medicines has been strengthened in recent years, and the recently revised Administrative Measures on Medicine Recalls stipulates new requirements for the recall system of pharmaceuticals. MAH, as the main body responsible for controlling the risk of medicines and eliminating the hidden dangers, has the obligation and responsibility to recall medicines which have been marketed and which have quality problems or other hidden dangers of safety, and the MAH should fulfil the obligation of the whole life cycle management of the medicines. The MAH shall collect relevant information on the quality and safety of medicines, investigate and assess possible quality problems or other hidden safety hazards, and take the initiative to recall any drug products with problems or hidden hazards. If the medicine is manufactured overseas, the local deputy designated by the overseas MAH to fulfil the MAH's obligations in China shall assume the responsibility for the recall and the corresponding reporting requirements. For recalled medicines, the MAH shall specify the labelling and storage requirements of the recalled medicines, and the relevant labelling and storage measures shall be clearly differentiated from normal medicines. In principle, the recalled medicines cannot be re-listed except for those that can be re-listed after appropriate treatment.

3. Regulator Engagement and Enforcement

3.1 Regulatory Authorities

Regulatory Authorities in Respect of Medical Devices and Medicines

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 and medicines, 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 and medicines 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 and medicines. 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 organisations, the CMDE and CDE, are respectively responsible for the technical evaluation of medical devices and medicines.

NHC

The National Health Commission (NHC) is a constituent department of the State Council and is mainly responsible for national health policies, the reform of the medical and healthcare system, disease prevention and control, health emergency response, national drug policies, and the national basic drug system. For blood products, NHC and its local counterparts are responsible for the supervision and administration on the collection and supply of source plasma, the manufacture, and distribution of blood products respectively at national and local levels. In addition, NHC and its local counterparts regulate the operation of medical institutions. For stem cells, NHC, the MOST, and the ethics committees of medical institutions are responsible for the ethical regulation of stem cell research; the NHC and the NMPA are responsible for the regulation of clinical research on stem cells. For human genetic resources, which was previously regulated by MOST, then the regulatory authority has been changed to the NHC according to the Decision of the State Council on Modifying and Repealing Some Administrative Regulations which released on 10 March 2024.

PSB

The Ministry of Public Security is a constituent department of the state council and, together with its local counterparts (collectively PSB), undertakes relevant responsibilities in the administration of special medicines. Specifically, as for narcotic drugs and psychotropic substances, while NMPA supervises from an overall drug perspective, PSB is responsible for investigating and regulating the flow of narcotic drugs and psychotropic substances.

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 the R&D of a medical device requires ethical review, in addition to the NHC, this may also be

subject to the administration of various regulatory authorities, including but not limited to the MOST, the Ministry of Industry and Information Technology (MIIT), the Ministry of Agriculture and Rural Affairs (MARA), the Ministry of Education and the State Administration of Traditional Chinese Medicine; 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, and cosmetic registration/recordation, to post-market risk management and supervision as well as inspection.
- The SAMR supervises and manages the business operation of cosmetics, and 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 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.

Besides, the MARA is a constituent department of the state council, and one of its important functions is to be responsible for the supervision and management of agricultural product quality and safety. For the regulation of GMOs, the MARA is the main department for the first phase of GMOs regulation (ie, GMOs raw materials) and is responsible for the supervision and management of the safety of agricultural GMOs throughout the country, and for the second phase of GMOs regulation (ie, labelling of GMOs), the MARA is responsible for formulating the relevant regulations on GMOs labelling and supervising it, with SAMR being responsible for the labelling of processed food with respect to GMOs.

3.2 Regulatory Enforcement Mechanisms

See **3.1 Regulatory Authorities**.

4. Liability

4.1 Product Safety Offences

The product safety offences exist in respect of the product categories listed in Section 1 are subject to applicable regulatory regimes. The liabilities and penalties for product safety offense are civil liabilities, administrative penalties and criminal penalties.

Civil Liabilities

In the event of product defects which cause damage to others or threaten the personal safety

or the property security of others, the producer or distributor of the products shall bear tortious liabilities 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 says 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.

Tortious Liability

Tortious 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 tortious liability. Therefore, generally in tortious 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 claims against product defects. According to the Civil Code, for product defects that have caused damage to others, the manufacturer or distributor shall bear strict liability. In other words, for claims against product defects, the plaintiff only needs to prove the following:

- the product has defects;
- damage occurred to the plaintiff; and
- a causal relationship exists between the product defects and the damage, although it is not required for the plaintiff to prove the intent or negligence of the defendant (the manufacturer or the distributor).

Technological advancements

Adopting new technologies does not change the basic legal framework for the above two liabilities.

As for products adopting new technologies, if they fall within the definition of a medical device, the legal framework under **1.1 Medical Devices** and guidelines specific to products, such as AI equipment and AI software, apply. Relevant MAHs are responsible for the quality management, safety, and effectiveness of the whole life cycle of such medical devices. Should defects be found in such products that cause damage to patients, the patients can request compensation from MAHs, producers, distributors, and/or medical institutions as the case may be based on tortious liability.

4.3 Judicial Requirements

Civil Action

For civil lawsuits concerning personal injury to others or damage to others' property caused by 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 a district, an intermediate, or a high People's Court or the 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 district 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 may be ruled by court to reimburse part of the costs paid by the prevailing party, including attorneys' fees, application fees for property preservation, translation fees, notary fees, appraisal, and assessment fees.

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, 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.

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:

- inadequacy of essential evidence;
- erroneous application of laws and regulations;
- violation of legal procedures;
- exceeding authority;
- abuse of power; or
- 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

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") 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, in a timely manner, 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 swiftly 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. Applicable Product Safety Regulatory Regimes

5.1 Policy Development

Medical Devices

In April 2024, the NMPA issued the Announcement on Further Strengthening the Supervision and Management of Entrusted Manufacturing by Registrants of Medical Devices, which requires medical device registrants to fully implement the main responsibility for the quality and safety of medical devices, and to establish a quality management system that covers the entire life cycle of the medical device and maintains effective operation. Medical device registrants who fail to comply with the requirements may be subject to liability interviews, and in serious cases, may be suspended from production, operation and use, and be subject to administrative fines. In addition, it intends to promote revisions to the Good Practice for the Quality Management of Medical Devices Sold Online, the Rules for the Classification of Medical Devices, and the Rules for On-Site Inspection of the Good Practice for the Quality Management of Medical Devices.

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 Objec-

tives 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 MIIT, it is stated that in respect of the use of big data, the development of technologically advanced software products is encouraged in key areas including medical care. It is anticipated that it will help promote the development of medical apps and possibly push the relevant legislation to adapt to the development of the industry.

Environmental policy and enforcement

In recent years, a number of listed companies, state-owned enterprises, and their subsidiaries in the pharmaceutical industry have been subject to administrative penalties for environmental issues, and the reasons for the penalties mainly include illegally discharging wastewater, exhaust gases and solid wastes exceeding the standards, and commencing work without EIA procedures. With regard to environmental issues in the pharmaceutical industry, in November 2023, the Ministry of Ecology and Environment (MEE) issued the Feasible Technical Guidelines for Pollution Prevention and Control in the Pharmaceutical Industry for API and preparation categories, and in May 2023, the MEE issued the Measures for Administrative Penalties Involving Ecology and Environment, which further emphasises the enforcement regarding environmental pollution. The Administrative Measures for Pollutant Discharge Licensing promulgated by the MEE in April 2024 may have an impact on issues such as the application for discharge permits and the approval and execution of such permits for pharmaceutical companies.

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.

In September 2023, the Medical Device Management Law was first included in the legislative plan of the Standing Committee of the NPC and meanwhile was one of the key legislative tasks of the SAMR 2024. Compared to RSAMD, the Medical Device Management Law has a higher tier of legal effect, elevating the management level of medical devices from an administrative regulation to a law. 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.

Human Genetic Resources

In March 2024, the State Council amended the Administrative Regulations on Human Genetic Resources, which mainly involves changes in the competent authorities for the management of human genetic resources, see **3.1 Regulatory Authorities**. It is foreseeable that, in order to realise the consistency of the various legal documents in the field of the regulation of human genetic resources, the Biosecurity Law, the Implementing Rules for the Regulations on Human Genetic Resources Management and the corresponding administrative guidelines will be amended accordingly.

Environmental Protection

In terms of environmental protection, the MEE 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. The NPC Standing Committee's 2024 Legislative Work Plan specifies that the legislation of the Ecological and Environmental Code will be promoted.

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; eg, the Administrative Measures for the Monitoring of Adverse Reactions of Cosmetics took effect from 1 October 2022, and the Cosmetic Inspection Regulations will come into effect on 1 November 2024. 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 2024 Work Plan for the Formulation of Regulations of the SAMR indicates that the SAMR proposes to formulate/revise the Supervision and Management Measures for Commissioned Production of Food, Supervision and Management Measures for Food Labelling, Supervision and Management Rules for the Implementation of the Main Responsibility for Food Safety by Food Production and Management Enterprise, etc.

5.3 Impact of Artificial Intelligence

Since 2016, China has enacted a number of laws and policies to encourage the deep integration of AI and healthcare. Currently, AI has had a positive impact on drug R&D, medical devices, health management, internet healthcare, and other fields. Specifically, AI technology has saved new drug development time and trial-and-error costs, promoted a number of new medical imaging devices, medical robots, and rehabilitation aids, provided intelligent solutions for daily health management and monitoring, and optimised the shortcomings of traditional internet healthcare in remote diagnosis and treatment.

Although China does not currently have a specific law on AI, the State Council has included a draft AI law in its legislative work plan for two consecutive years in 2023 and 2024 as an item to be submitted to the Standing Committee of the NPC for consideration. China has also issued specialised management measures on generative AI services, and prohibits the use of AI to automatically generate prescriptions. With regard to pharmaceuticals, the NMPA recently issued the List of Typical Application Scenarios of Artificial Intelligence for Drug Regulation, which sets out detailed provisions for 15 application scenarios in four categories, aiming to promote the deep integration of artificial intelligence and drug regulation. The application scenarios listed in the category of daily supervision include remote supervision, on-site supervision, assisting sampling work, assisting in auditing cases, pharmacovigilance, and network transaction supervision. The MOST issued the Ethical Guidelines for Brain Computer Interface (BCI) Research in February this year, aiming at guiding the conduct of related research in a

compliant manner and preventing ethical risks in science and technology. Various localities have also made relevant regulations in the field of AI, such as Beijing, which issued the Guidelines for Inspection of Quality Management Standards for the Production of Artificial Intelligence Medical Devices. In addition, some chapter provisions in the laws of various specialised fields will provide for AI, such as the Personal Information Protection Law, which explicitly requires the formulation of special personal information protection rules and standards relating to AI.

As AI laws and regulations develop, they will have a continuing and far-reaching impact on the current legal frameworks governing medical devices and consumer health products. First, AI laws and regulations will be continuously updated as AI technology gives rise to new products or involves new issues, such as the release of many new regulations on medical AI software in recent years, so the content of the current legal frameworks will be further enriched, and the corresponding compliance obligations may further increase. Second, AI laws and regulations need to respect the nature of AI technology, and the basic concepts of the current legal frameworks may be changed, such as how the determination of the subject qualification of medical robots will determine whether they are the subject of tort liability, and ultimately affect the allocation of the tort liability.

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