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Heathcare: Medical Devices 2026

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China: Law and Practice

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CHINA

Law and Practice

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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. Global Law Office (GLO) has become one of the largest, leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen, Chengdu and Suzhou offices. Its life sciences and healthcare (L&H) practice group was one of the first in China and provides "one-stop" legal services for every area of the industry, including M&A, investment and funding, licence in and out, daily operation, IP protection, labour and employment and advice on compliance, including internal and government investigations, 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. The team participates extensively 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 act as auxiliary functions.

Medical devices are strictly regulated in the PRC according to their classification, and 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, its 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 have a low degree of risk;
- Class II medical devices have a medium degree of risk; and
- Class III medical devices have the highest risk level.

Class I medical devices are subject to record-filing administration, and Class II and Class III medical devices are subject to registration administration.

Regulation 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 are further regulated by good practice rules and administrative measures, such as Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Supply Practice (GSP) for Medical Devices.

Subject to the classification, the registrants or record-filing holders – analogous to marketing authorisation holders (MAHs) – are responsible for whole life cycle quality management, and for the safety and effectiveness of the medical devices throughout their development, manufacturing, distribution and use.

Software-Based Medical Devices

See **1.4 Technologies and Digital Health**.

Personal Protective Equipment (PPE)

PPE is not a defined legal term under PRC laws. 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.

There are specific requirements for "special labour protection articles", such as safety helmets. The current regulations on special labour protection articles are less stringent than the regulations for medical devices, while general labour protection articles and other PPE are deemed to be ordinary products with no special regulatory requirements.

In Vitro Diagnostics (IVD) Reagents

"In vitro diagnostic reagents" refers to IVD reagents regulated as medical devices, including reagents, reagent kits, calibrators, quality control products and other products used for the in vitro testing of human specimens in the processes of disease prediction, prevention, diagnosis, therapeutic monitoring, prognosis evaluation and health status assessment. To clarify, IVD reagents for blood screening and IVD reagents labelled with radionuclides are subject to drug supervision rules.

In addition to general medical device requirements, IVD reagents are subject to special supervision covering non-clinical studies, clinical evaluation and quality control.

1.2 Healthcare Products

Product Safety Regulatory Regime for Healthcare Products

Cosmetics

Cosmetics are governed by administrative regulations, covering manufacturing, marketing, business operation and post-market monitoring. The Regulations on the Supervision and Administration of Cosmetics (RSAC) apply a Classification Supervision System, as follows:

- special cosmetics (ie, those used for hair colouring, hair perming, freckle removal and whitening, sun protection and hair loss prevention) and those that claim new efficacy must be registered with the competent authorities before manufacturing and import; and
- ordinary cosmetics (ie, cosmetics other than special cosmetics) only need to be record-filed prior to being marketed or imported.

Biocides

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, corresponding licences must be obtained from the competent authorities for the manufacturing, marketing and business operation of pesticides.

Food

Food is classified as either conventional food or special food, with the latter covering health food – ie, food with specific healthcare functions suitable for specific groups of persons due to its body-regulation functions but not for the purpose of disease treatment, including nutrition supplements. The Food Safety Law (FSL) regulates the production, distribution, safety, labels, inspection, and import and export of food products. In addition to complying with the FSL requirement, certain food categories are subject to specific regulations, as specified below:

- Genetically Modified Organisms (GMOs) are further regulated by the Regulations on Administration of Agricultural Genetically Modified Organisms Safety;
- novel foods are further regulated by the Administrative Measures for Safety Review of Novel Food Raw Materials; and
- nutrition supplements are further regulated by the Catalogue Management System under Administrative Measures for the Catalogue of Health Food Raw Materials and the Catalogue of Healthcare Functions.

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 and the GCP outline the framework for pharmaceutical clinical trials, specifying the obligations of the parties involved, operational procedures and technical requirements.

Off-label use of pharmaceuticals is stipulated in the Physician Law, and is permitted only if all of the following three conditions are satisfied:

- no effective or superior alternative treatment is available, or under other special circumstances;
- the off-label use is supported by evidence-based medical proof; and
- explicit informed consent is obtained from the patient.

Details on the regulation of pharmaceuticals and relevant clinical trials can be viewed in the China Law and Practice section in the 2026 Chambers Life Sciences Global Practice Guide.

Vaccines

"Vaccines" refer to prophylactic biological products for human immunisation for the prevention and control of diseases, including immunisation programme vaccines and non-immunisation programme vaccines. In addition to the laws and regulations generally applicable to drugs and infectious diseases, vaccines are also subject to the Vaccine Administration Law (VAL) and other special regulatory requirements, such as priority review and approval procedures, batch release administration, electronic traceability and prohibition of online sales.

Orphan Drugs

"Orphan drugs" is not a defined legal term under PRC law, and generally refers to pharmaceuticals developed for the prevention, diagnosis and treatment of rare diseases. The scope of rare diseases is subject to the Catalogue of Rare Diseases published by the National Health Commission (NHC) and other administrative authorities.

Subject to all generally applicable pharmaceutical laws and regulations, orphan drugs are entitled to dedicated incentives and expedited approval policies.

Blood Products

Under the PRC's legal regime, blood products refer in particular to various human plasma protein products, which are governed as pharmaceuticals and as biological medicinal products. As a special category of medicinal products, in addition to the laws and regulations generally applicable to drugs, blood products are also subject to the Regulations on the Administration of Blood Products and other special regulatory requirements, such as source plasma, batch release administration and prohibition of online sales.

Psychedelics

"Psychedelics" is not a defined legal term under PRC law. Certain psychedelics, if used properly, may function as a psychotropic substance. If such psychedelics further fall within the Catalogue of Psychotropic Substances, they are eligible to be applied under the administration of the NMPA and registered as a drug subject to regulation. Under PRC law, psychotropic substances are categorised and regulated based on their risk level, from high to low, into Class I and Class II.

In addition, psychotropic substances are subject to the Regulations on the Administration of Narcotic Drugs and Psychotropic Substances. Their R&D and manufacturing require special approval, and they 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 under the NMPA's List of Prohibited Raw Materials for Cosmetics. Cannabidiol is also listed in the Catalogue of Class II Precursor Chemicals and is subject to the Regulations on the Administration of Precursor Chemicals. Preclinical research on CBD for medical purposes must satisfy specific regulatory conditions and obtain NMPA approval.

1.4 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

Medical device software can be divided into two main categories:

- Software as a Medical Device (SaMD); and
- Software in a Medical Device (SiMD).

SaMD

SaMD refers to software that is intended to be used for one or more medical purposes, and that performs these purposes without being part of a hardware medical device. There are two types of SaMD.

- Generic SaMD 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 SaMD is generally registered as a medical device separately.
- Dedicated SaMD 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 part of a hardware medical device. If registered as part of a hardware medical device, it will be regarded and regulated as a software component, rather than as a medical device.

SiMD

SiMD refers to software intended for one or more medical purposes that controls or drives a hardware medical device or runs on a dedicated/medical computing platform. As a component of a medical device, SiMD shall be registered not independently but together 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 or heart-rate monitors for exercise.

Telemedicine

A telemedicine information system is used for telemedicine services. Equipment in the telemedicine information system that meets the definition of a medical device is regulated as a medical device. According to Good Practices for Telemedicine Services (for Trial Implementation), the system shall ensure that images, sounds, texts and other required medical information are transmitted safely and in time, with clear images and accurate data, and shall conform to the Technical Guidelines for Construction of the Telemedicine Information System and meet the requirements of clinical diagnosis.

Personalised Medicine

"Personalised medicine" is not a defined legal term under PRC law. In practice, its core applications include but are not limited to genetic sequencing and stem cell-based therapies.

Gene sequencing

Gene sequencing products (including gene sequencers, corresponding diagnostic reagents and software) that perform in vitro testing on human specimens and meet the definition of medical devices as discussed in **1.1 Medical Devices** are classified and regulated as medical devices.

Stem cells

Stem cells are self-renewing, highly proliferative cells that can further differentiate into various tissue cells.

Different categories of stem cells are under different types of regulations:

- stem cells that can be produced in a standardised and large-scale manner are categorised as drugs and regulated by the NMPA; and
- stem cells within the scope of the Guiding List for Clinical Research Filing of New Biomedical Technologies are categorised as new biomedical technologies and regulated by the NHC.

1.5 Borderline Products

Medicines and Medical Devices

In practice, products with features of both medicines and medical devices will be categorised as either, depending on their characteristics.

For a combination product (ie, a medical product containing both a drug and a device), applicants should apply for registration as a drug or as a medical device according to its principal mode of action. A combination product that mainly acts as a medical device shall be managed as a Class III medical device. If its major utility cannot be easily identified, the applicant should apply to the NMPA's Centre for Medical Device Standardisation Administration to define the product's characteristics before applying for registration.

Medical Devices and Lifestyle Products

In contrast to the medical devices mentioned in **1.1 Medical Devices**, lifestyle products refer to products purchased and used by consumers for daily consumption needs, which are subject to Product Quality Law and Consumer Rights Protection Law.

PPE and Medicines

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/Food Supplements

Although food supplements may claim certain health protection functions, the FSL stipulates that food (including food supplements) excludes substances that are used for the purpose of treatment, and further stresses that labels and descriptions of food supplements shall not refer to any preventative 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, whether for clinical use or commercialisation, must comply with the RSAMD, the Measures for the Supervision and Administration of Medical Device Manufacture and GMP in the PRC. Notably, the newly revised GMP (2025 Edition), effective 1 November 2026, introduces significant updates.

- For manufacturing sites, the premises shall meet the manufacturing requirements – eg, the production area shall suit the scale of production and product varieties; the overall layout of the production, administrative and ancillary areas shall be reasonable; and such areas shall not interfere with each other.
- For design and development planning, a manufacturer shall set out the design and development stages as well as the review, verification, validation and design transfer activities to be performed at each stage, which shall be approved and periodically reviewed during implementation. Design and development inputs shall cover functional, performance and safety requirements, regulatory requirements and risk control measures. Outputs must meet the input requirements, including 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 equivalent at least to the lifespan of the medical device and for not less than two years from the date of product release.

In addition to the above-mentioned GMP requirements, a manufacturer of medical devices must obtain a licence or record-filing before it manufactures medical devices for commercialisation. The requisite permits vary by classification: manufacturing Class I medical devices requires a record-filing receipt, while manufacturing Class II and/or Class III medical devices requires a licence.

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. Prior to engagement, the MAH shall assess the manufacturer's production and quality assurance capabilities on-site. Both parties shall enter into a Quality Agreement and an entrusted manufacturing contract to prescribe the responsibilities of each party, especially the responsibilities and liabilities for product quality assurance. For Entrusted Manufacturing, the entrusted manufacturer shall perform release procedures, while the entrusting party shall exclusively perform market release procedures, which shall not be further delegated.

Healthcare Products

Unless the law and regulation provide otherwise, a licence for manufacturing is a prerequisite for the production of cosmetics and food. Manufacturers of cosmetics and food must follow the respective manufacturing requirements.

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.

Food production must conform to the requirements stipulated by the FSL and a whole set of national standards regarding food safety.

Special Regulations for Medical Apps

With respect to medical apps, the NMPA has issued special regulations for the manufacture of SaMD, such as the Appendix for SaMD to GMP (the "Appendix") and GMP – Guidelines for On-Site Inspection of SaMD.

The Appendix applies to SaMD and applies mutatis mutandis to SiMD. According to the Appendix, the special requirements cover aspects such as personnel, equipment, design development, procurement, manufacturing management, quality control, sales and after-sales service, and monitoring, analysis and improvement of adverse events.

Special Rules and Standards for Wearables

For wearables that meet the definition of medical devices and are regulated as medical devices, the NMPA issued the Guidelines for Registration Review of Mobile Medical Devices (2025 Revised Edition) in 2025, which specifically applies to wearable mobile medical devices such as smart glasses and smart watches. The 2025 revision introduces refined technical considerations for R&D and registration.

2.2 Corporate Social Responsibility, the Environment and Sustainability

There is a national trend towards strengthening the legislation on corporate social responsibility. The Company Law requires companies to take account of the interests of employees, consumers and the public, such as ecological and environmental protection, and to assume social responsibility. Furthermore, the revised Measures for the Administration of Information Disclosure by Listed Companies, effective from 1 July 2025, elevate sustainability reporting to the level of departmental regulation, mandating that listed companies within the compulsory disclosure scope publish sustainability reports, and subjecting non-compliance to regulatory measures such as rectification orders and regulatory talks.

In December 2025, the nine ministries further issued the first specific standard under the national unified disclosure framework: the Enterprise Sustainable Disclosure Standards No 1 – Climate (Trial). Entities involved in the life cycle of medical devices and healthcare products must meet general statutory obligations for environmental protection under the framework of the 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. In addition, the manufacturer must apply for a pollutant discharge permit or fill in a pollutant discharge registration form.

As kinds of electrical or electronic products, wearables shall be subject to the Prevention and Control of Environmental Pollution Caused by Solid Wastes Law of the PRC, and the Regulation on the Administration of the Recovery and Disposal of Waste Electrical and Electronic Products. Furthermore, GB 26572-2025 Requirements for the Restriction of Hazardous Substances in Electrical and Electronic Products will become mandatory in 2027, replacing the former recommended standard GB/T 26572-2011. The scope

of restricted substances has been expanded from six to ten, adding four phthalates (DBP, DIBP, BBP and DEHP) and aligning with the EU RoHS Directive. Producers of wearables must ensure that product design and material selection comply with these mandatory substance restrictions.

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. In addition to the 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; a draft to replace this interim version was released for comment in 2026) also set out detailed requirements regarding how medical devices are advertised and the content of such advertisements. Medical devices used for the treatment of addiction, or whose production, sale or use is ceased or prohibited, may not be advertised. In addition, advertisements for medical devices are not allowed to be published in public media that targets minors.

The 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 and clearly indicated on the advertisement. 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 which case prior approval is not required. The Guidelines on the Application of the Advertising Law (I), issued in July 2025, clarify the boundary between commercial advertising and objective information display.

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.

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

Advertisements for medical devices shall 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;
- contain guarantees of the medical device’s efficacy or the cure of disease, or guarantees by implication of the cure of disease; or
- contain any inducements such as “hot sales”, “rush to buy”, “trial”, “family necessities”, “free treatment” or “free gifts”, nor any comprehensive evaluations such as “comparison”, “ranking”, “recommendation”, “designated”, “selected” or “awards”, nor any warranties such as “refund upon ineffectiveness” or “insured by insurance companies”.

Healthcare Products

All commercial advertisements for healthcare products are subject to the Advertising Law and shall be true, accurate and free from any false or misleading information. Advertisements for cosmetics and food are prohibited from indicating any disease treatment and from using medical terms that might cause confusion with drugs or medical devices.

Cosmetics advertisements must comply with the Regulations on the Supervision and Administration of Cosmetics and the Cosmetics Efficacy Claims Evaluation Specification, and all efficacy claims must be scientifically supported.

Health food advertisements are subject to the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Health Food and Foods for Special Medical Purpose and require prior review and approval. Other key requirements include that:

- advertisements must conform to the registered or filed contents; and
- advertisements for health food must:
  (a) prominently display the warning that health foods are not drugs and cannot treat any disease instead of drugs;
  (b) be marked with the official logo of health food; and
  (c) indicate the suitable and unsuitable consumers.

Internet Advertising

Advertising on medical apps constitutes internet advertising, subject to the Measures for the Administration of Internet Advertising. All such advertisements shall be identifiable and clearly labelled with the word "Advertisement" in Chinese, to enable consumers to clearly recognise their advertising nature. Paid search results must be distinguished from natural search results, and the publication or transmission of such advertisements must not affect users' normal use of the internet. Pop-up, splash screen or other forms of advertisements must display a prominent "close" sign ensuring one-click closure, without requiring multiple clicks or timed delays.

2.4 Marketing and Sales

Clinical Evaluation of Medical Devices

Pre-market clinical research and the design of medical devices are governed by the RSAMD (as revised in December 2024) and the Administrative Measures for the Registration and Record-filing of Medical Devices (MDRM), which establish the legal framework for pre-market R&D.

According to the RSAMD and the MDRM, the registration/record-filing of medical devices is subject to clinical evaluation, except for limited circumstances where:

- 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
- the medical device has been proved in other ways to be safe and effective through non-clinical evaluation.

The NMPA also promulgates a list of medical devices that are exempt from clinical evaluation, which was most recently updated in May 2025.

Clinical evaluation can be carried out through clinical trials, or through analysis of clinical literature and data of the same variety of medical devices; a clinical trial should be implemented where existing literature and data are insufficient.

In addition to the RSAMD and the MDRM, the GCP and the Inspection Points and Determination Principles for Clinical Trial Projects of Medical Devices (effective on 1 May 2025) govern the conduct of clinical trials.

The sponsor must ensure that clinical trial data is true, accurate, complete and traceable, and retain basic clinical trial documents until the device is no longer marketed. Trials involving human genetic resources and international co-operation require filing with or prior approval from the NHC, particularly where such materials will be exported.

Registration/Record-Filing of Medical Devices

To apply for the registration/record-filing, the applicant must generally conduct clinical evaluation, through either pre-market non-clinical research or clinical trials.

The medical device will be granted an authorisation or record-filing certificate by the NMPA or its local counterparts based on its classification (see **1.1 Medical Devices**). On 30 December 2025, the NMPA adjusted the Catalogue of Medical Device Classification for 31 categories (Announcement No 132 of 2025), affecting the classification and regulatory pathway of certain products. For a newly developed medical device not

listed in the Catalogue of Medical Device Classification, the applicant may either apply directly for registration as a Class III medical device, or first apply to the NMPA for classification and then apply for registration/record-filing. 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 the device's 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. The distribution of Class I medical devices is not subject to special authorisation. The registrant/record-filing holder may distribute the medical devices itself or entrust a qualified third-party distributor to do so.

The distribution must comply with GSP throughout procurement, acceptance, storage, sales, transportation and after-sales services. The distributor must keep records covering the full operation process; these records must be kept for two years after the life span, or for at least five years where no life span is specified. For an implantable medical device, the records must be kept permanently.

Online sales of medical devices are generally permitted subject to filing. The online distributor (self-operated platform) or the platform provider (third-party platform) must file with the competent Medical Products Administration (MPA). The online distributor must also comply with the GSP for Online Sales of Medical Devices (effective on 1 October 2025).

Special Requirements for Healthcare Products

For cosmetics, in the pre-market stage, a complete product safety assessment must be conducted under technical guidelines such as the Technical Guidelines for Cosmetic Safety Assessment, assessing the potential safety risks of each raw material and/or hazardous substance; the resulting report is a mandatory submission for registration/record-filing.

In terms of food, pre-market requirements mainly involve product registration/filing of health food, a marketing business licence and a safety assessment. Health food is under a special regulation requiring its registration or record-filing, as follows:

- 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 that are being imported for the first time must be record-filed with the competent authority before production and import.

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

As with medical devices, all medicines must be registered with the NMPA before launch. Generally, each drug product must go through three phases of clinical trials, generating sufficient safety, validity and efficacy data before the MAH submits the new drug application; each trial requires filing with the NMPA and a permit.

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, the design development requirements are the main pre-market requirements for SaMD.

With respect to sales and after-sales services, the Appendix requires the deployment and discontinuation of the software to be documented. Deployment activities, such as delivery, installation, configuration and user training, must be documented or recorded. As for discontinuation of the software, records of the following situations and activities shall be kept:

- subsequent user services after the discontinuation;

- data migration;
- protection of patient data and privacy; and
- user notification.

Regarding adverse events, the Appendix requires enterprises to set up data analysis control procedures covering software defects and cybersecurity incidents, and to document emergency responses, including user notification, recall and risk management.

2.5 Internationalisation

Internationalisation plans are influenced not only by market access, customs and trade control issues, but also by the strength and enforcement posture of the PRC regulatory regime: product classification, registration/filing, quality management, post-market surveillance, customs inspection, export controls, technology export restrictions and data or human genetic resources export requirements may all affect timing and transaction structure. Manufacturers should also take product liability exposure in China into account, including jurisdiction and cost risks, as discussed in **4. Liability**. The key internationalisation issues are as follows.

Potential Restriction on Exporting Medical Devices or Related Technologies

Under the Foreign Trade Law, the Export Control Law and the Regulations on Export Control of Dual-Use Items, an authorisation administration mechanism has been implemented for the export of dual-use biological goods and related equipment and technologies listed in the Export Control List of Dual-Use Items, the Catalogue for the Administration of Import and Export Authorisation for Dual-Use Items and Technologies, or otherwise subject to export control or licensing requirements under PRC export control laws and regulations (collectively, the Control List). 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.

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 export of 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 via 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. Under the NMPA's Announcement on Further Adjusting and Optimising Domestic Production for Imported Medical Devices, an imported Class II or III medical device can be manufactured within the PRC through a simplified procedure if the domestic manufacturer is invested in by, or under the same ultimate controller as, the overseas registrant. Provided that the design and quality system remain basically consistent and the safety and effectiveness are not significantly changed, the original registration application materials for the imported device will be recognised by the NMPA.

Cross-border entrustment of manufacturing of 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 to manufacture such medical devices. Pursuant to policy measures issued in 2025, a pilot programme for cross-border contract manufacturing of medical devices is currently under exploration in Beijing and Jiangsu.

Healthcare Products

The importation and exportation of cosmetics and food should also comply with the following special regulations:

- 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.

Stem Cell Technology

Although foreign investment is prohibited in the development and application of human stem cell or related technology under the Special Administrative Measures (Negative List) for Foreign Investment Access, foreign invested enterprises in the Beijing, Shanghai or Guangdong Pilot Free Trade Zones or the Hainan Free Trade Port may engage in human stem cell, gene diagnosis and gene therapy technology development and application solely for product registration and manufacture. Stem cell-based products duly registered, marketed and approved for production may be deployed nationwide.

In addition, the Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies (State Council Order No 818), promulgated in 2025 and effective from 1 May 2026, has established a separate regulatory pathway for the clinical research and clinical translational application of new biomedical technologies. The 818 regime generally applies to highly innovative or personalised biomedical technologies applied as medical technologies in qualified medical institutions; technologies or products with a clear drug or medical device product form should continue to follow the drug or medical device regulatory pathway.

Value-Added Telecommunications Services

If a medical app involves value-added telecommunications services, the foreign equity of the company is generally restricted to no more than 50% in accordance with the Special Administration Measures (Negative List) for Foreign Investment Access. However, foreign equity ratio restrictions on related businesses have been removed on a pilot basis. Following the launch of pilot programmes in specific regions in Beijing, Shanghai, Hainan and Shenzhen in 2024, the pilot scope was further expanded in 2025 to include nine additional cities. As of June 2026, 166 foreign-invested enterprises had obtained pilot approvals to operate value-added telecommunications services in China.

2.6 Post-Marketing Obligations, Including Corrective Actions and Recalls

Post-Marketing Obligations Regarding Medical Devices

Under the RSAMD and related laws and regulations, the MAH is responsible for the following post-marketing obligations.

- Establishing and maintaining a quality management system – the MAH is responsible for whole life cycle quality management and record-keeping (see **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 shall submit reports of such inspections, as required.
- Setting up and implementing the post-marketing research and risk management and control plan – the MAH shall proactively carry out post-marketing research to further confirm the safety, effectiveness and quality controllability of medical devices.
- Monitoring and re-evaluating medical device adverse events (AEs) – under the Administrative Measures for Medical Device-Related Adverse Event Monitoring and Re-evaluation, the MAH shall establish an AE monitoring system and:
  (a) be equipped with organs and personnel for medical device-related AE monitoring work; and
  (b) proactively collect and truthfully report any

medical device-related AEs to the monitoring institutions 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.
- Proactively carrying out medical device re-evaluation, including where triggered by statutory circumstances.
- 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. If the MAH finds that medical devices do not meet mandatory standards or the registered or filed technical requirements, or have other defects, it shall immediately stop production, notify distributors, users and patients to stop distribution and use, recall marketed devices, take remedial or destruction measures, record and release relevant information, and report to the competent authorities; any manufacturer or distributor that finds such circumstances must stop manufacturing or distribution and notify the MAH.

In addition to the above post-marketing obligations, the revised Medical Device Production Quality Management Specification (2025 Edition) further specifies quality system requirements relating to post-market quality information.

For digital healthcare products and new technologies, the applicable post-marketing obligations depend on their regulatory classification. Where they are regulated as medical devices, including SaMD or SiMD, the medical device post-marketing regime applies.

Healthcare Products

Cosmetics and food products are highly regulated in respect of post-marketing, with product recall being one of the key regulatory mechanisms. For cosmetics, the post-marketing regime also includes adverse reaction monitoring and reporting, regulatory safety risk monitoring and evaluation, record-keeping, risk control and consumer notification. The Measures for the Administration of Cosmetics Safety Risk Monitoring and Evaluation (effective 1 August 2025) further specify the mechanism for identifying, evaluating and responding to cosmetic quality and safety risks. For food products, post-marketing obligations include food safety traceability, record-keeping, self-inspection, risk reporting, recall and consumer notification.

Registrants, filers, manufacturers or business operators of cosmetic products that find any defects or other matters harmful to human health should cease manufacture and recall marketed products.

Food manufacturers that find products fail to meet food safety standards or may be harmful to human health must immediately cease manufacture and recall marketed products; business operators must notify the manufacturers to cease manufacturing.

Post-Marketing Obligations Regarding Medicines

The Administrative Measures on Medicine Recalls stipulate requirements for the recall system of pharmaceuticals. As the main body responsible for controlling medicine risks, the MAH must fulfil whole life cycle management obligations: collecting quality and safety information, investigating and assessing possible quality problems or hidden safety hazards, and taking the initiative to recall any drug products with problems or hidden hazards.

If the medicine is manufactured overseas, the domestic agent 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 labelling and storage requirements 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. Furthermore, the MAH shall conduct regular post-market launch appraisal of the safety, effectiveness and quality controllability of the drugs launched to market.

3. Regulator Engagement and Enforcement

3.1 Regulatory Authorities

Regulatory Authorities in Respect of Medical Devices and Medicines

The SAMR

The SAMR is the national authority for market supervision, administration and law enforcement relating to medical devices and medicines, particularly in respect of product quality safety, business registration and certification, advertising, anti-monopoly and unfair competition (including commercial bribery). The Administrations for Market Regulation (AMR) at the provincial, city and county levels handle day-to-day law enforcement. The SAMR and AMRs are also responsible for the administration and supervision of the production, distribution and use of PPE.

The NMPA

As a national bureau under the SAMR's supervision, the NMPA regulates the registration, post-marketing risk management, safety and quality administration, standard-setting, and supervision and inspection of medical devices and medicines, and authorises local MPAs to issue certain filing receipts and manufacturing and distribution permits.

The NMPA's affiliated organisations, the CMDE and CDE, are responsible for the technical evaluation of medical devices and medicines, respectively.

The NHC

The 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, the NHC and its local counterparts supervise the collection and supply of source plasma and the manufacture and distribution of blood products, and also regulate the operation of medical institutions.

The NHC, the Ministry of Science and Technology (MOST) and the ethics committees of medical institutions are responsible for the ethical regulation of stem cell research; the NHC and the NMPA regulate clinical research on stem cells. The regulatory authority for human genetic resources was changed from MOST to the NHC in 2024.

PSB

The Ministry of Public Security and its local counterparts (collectively PSB) administer special medicines: for narcotic drugs and psychotropic substances, the NMPA supervises from an overall drug perspective, while PSB investigates and regulates their flow.

Other regulatory authorities

Other regulatory authorities may also be involved in the relevant administration if certain activities or matters fall under their powers – eg, the Ministry of Industry and Information Technology (MIIT) regulates personal information protection, and the Ministry of Agriculture and Rural Affairs (MARA) administrates medicinal original plants for narcotic drugs; see **2.4 Marketing and Sales**.

Healthcare Products

Cosmetics

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

- the NMPA governs cosmetics safety and quality supervision, standards, registration/record-filing, post-market risk management and inspection; and
- the SAMR supervises and manages the business operation of cosmetics, and investigates and punishes violations such as illegal advertisements, unfair competition and infringement of consumer rights, with day-to-day enforcement by local AMR departments.

Food

The authorities governing food include the NHC and the SAMR:

- the SAMR supervises and manages food production, circulation and catering services, with day-to-day enforcement by local AMR departments; and
- the NHC is responsible for formulating food safety standards and conducting food safety risk monitoring and risk assessment.

The MARA is a constituent department of the State Council, and its functions include the supervision of agricultural product quality and safety. For agricultural GMOs as raw materials, the MARA administers the relevant labelling, R&D, manufacture and distribution. For processed food relating to GMOs, the SAMR is the main administrative authority.

3.2 Regulatory Enforcement Mechanisms

See **3.1 Regulatory Authorities**.

4. Liability

4.1 Product Safety Offences

Product safety offences in respect of the product categories listed in **1. Applicable Product Safety Regulatory Regimes** are subject to the applicable regulatory regimes. Depending on their nature and consequence, such offences may give rise to civil liabilities, administrative penalties or criminal penalties.

Civil Liabilities

In the event of product defects that cause damage to others or threaten the personal safety or property security of others, the producer or distributor shall bear tortious liabilities such as:

- cessation of infringement;
- removal of obstacles;
- elimination of danger;
- compensation; and
- punitive damages.

Administrative Penalties

A medical device company that commits illegal acts, including violations of the RSAMD or other applicable laws, may be subject to administrative penalties by the competent authorities. Under 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;
- ordering the company to suspend the production or operation of medical devices;
- revoking administrative permission; and
- rejecting applications for medical device permits.

Responsible personnel may face fines, administrative sanctions, confiscation of income earned from the entity during the relevant period, and prohibition from medical device production or operation for a specific period or for life.

The NMPA and local MPAs continue to publish typical cases or examples of the administrative penalties from time to time.

Criminal Penalties

Illegal acts involving criminal offences may subject responsible individuals to criminal detention, fines, confiscation of property and fixed-term 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 tortious liability.

Contractual Liability

Under the Civil Code, a party that fails to perform its contractual obligations, or whose performance does not conform to the contract, bears liability for breach, such as continuing performance, taking remedial measures or compensating for losses.

Tortious Liability

Tortious liability is also provided in the Civil Code: a person at fault in infringing upon another's civil rights and interests and causing damage shall bear tortious liability. In a tortious liability claim, the plaintiff generally needs to prove the defendant's fault. In product defect claims, however, the Civil Code requires the plaintiff to prove only the following, without proving the defendant's fault:

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

Technological Advancements

Adopting new technologies does not change the basic civil liability framework for contractual liability or tortious liability.

If products adopting new technologies fall within the definition of a medical device, the legal framework outlined under **1.1 Medical Devices** and guidelines specific to products such as AI equipment and AI software apply. Relevant MAHs remain responsible for whole life cycle quality management, safety and effectiveness. Should defects cause damage to patients, compensation may be claimed from MAHs, producers, distributors and/or medical institutions, as the case may be, based on contract or tort rules.

4.3 Judicial Requirements

Civil Action

For civil lawsuits concerning personal injury or property damage caused by product quality issues, the People's Court at the defendant's domicile, or at the place where the product is manufactured or sold or the tort was committed, has jurisdiction.

Criminal Action

Generally, the People's Court where the crime was allegedly committed has jurisdiction; the People's Court of the defendant's place of residence may also have jurisdiction if more appropriate.

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 supervision of product quality within its administrative region.

4.4 Costs

When consumers or injured parties prevail in product liability cases, the losing party must pay the litigation fee and/or property preservation fee to the court, and may also be ordered to reimburse part of the prevailing party's costs.

4.5 Product-Related Contentious Matters

Adverse Events

For AEs causing sudden or mass severe injury or death, provincial MPAs and/or the NMPA shall organise timely investigations together with the Health Commission at the same level, and handle such AEs under the RSAMD and other applicable regulations.

Product-Related Contentious Matters

Product-related contentious matters may involve forensic identification to identify and determine specialised issues or obtain expert opinions on contentious matters in accordance with the General Rules on Procedures for Forensic Identification and relevant regulations.

For product-related disputes between consumers and business operators, consumers may lodge complaints with the administrative authorities under the Law on the Protection of Rights and Interests of Consumers and the Measures for the Handling of Complaints and Whistle-blowing Reports on Market Regulation.

Unfair Competition

Any organisation or individual may report alleged unfair competition by business operators to the regulatory authorities under the Anti-Unfair Competition Law of the PRC, and other suspected violations under the Provisional Measures for the Handling of Complaints and Whistle-blowing Reports 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
- for ordinary joint actions, the parties must agree to adopt a joint trial.

If a medical device-related case meets the above circumstances, it may proceed as a joint action.

Representative Action

There has been no medical device-related representative action in China to date, but several government documents have called for exploration of a consumer representative action system.

Public Interest Action

In China, state organs and relevant organisations may sue before the People's Court against acts harming the public interest, such as environmental pollution and infringement of consumers' legal rights and interests; the People's Procuratorate may also bring lawsuits over torts against consumers in the field of food and medical product safety. In practice, public interest actions have been brought against medical device manufacturers and healthcare product distributors, while representative actions or other joint proceedings remain uncommon, and any future increase is likely to be gradual.

4.7 ADR Mechanisms

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

The China Consumers Association and local consumer associations receive consumer complaints regarding product quality and other product or service issues, and conduct investigations and provide mediation support under the PRC Law on the Protection of Rights and Interests of Consumers and its implementing regulation.

4.8 Interrelation Between Liability Mechanisms

Case Referral Between Judicial Authorities and Administrative Authorities

In accordance with the Administrative Penalty Law of the PRC, an administrative authority must refer an illegal act suspected of constituting a crime to the judicial authority for criminal liability investigation, and the judicial authority must promptly refer back cases that do not require criminal liability or are exempted from criminal punishment but may attract administrative penalties. A civil product liability proceeding does not itself trigger a criminal proceeding, but suspected criminal facts identified in civil, administrative or regulatory proceedings may be referred to the competent authorities.

Judicial Review of the Administrative Act

Under the Administrative Procedure Law of the PRC, the court may overturn or partially overturn an administrative act, or require a new act, where any of the following applies:

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

An obviously unfair administrative sanction, or an administrative act with a definite error regarding the amount of money, 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 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, judicial authorities and public security organs.

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

Relevant documents of the NMPA urge local MPAs to closely co-operate with local PSBs and AMRs. A local MPA must timely refer any monopoly, illegal advertisement, unfair competition or other illegal act to the competent AMR, and any suspected crime to the competent PSB; in cross-regional cases, local authorities must co-operate closely in investigation and punishment.

5. Applicable Product Safety Regulatory Regimes

5.1 Policy Development

Medical Devices and Pharmaceuticals

In December 2024, the General Office of the State Council issued the Opinions on Comprehensively Deepening the Reform of Regulation of Pharmaceuticals and Medical Devices to Promote the High-quality Development of the Pharmaceuticals Sector, which sets the following goals to be met by 2027:

- the framework of laws and regulations for pharmaceuticals and medical devices will be further improved;
- the regulatory system, mechanism and methods shall be better aligned with the needs of pharmaceutical innovation and high-quality development;
- the quality and efficiency of review and approval for innovative drugs and medical devices will be markedly enhanced;
- the entire life cycle regulation shall be strengthened significantly; and
- quality and safety levels will be comprehensively elevated.

Healthcare Products

Under the Implementation Opinions on Comprehensive Strengthening of the Capacity Building in Drug Supervision, enhancing cosmetic risk-monitoring capacity is a key short-term policy priority.

Food safety is the spotlight of the policy. The Outline of the People's Republic of China 15th Five-Year Plan for National Economic and Social Development sets out the goals to improve the whole-chain and whole-process supervision mechanism and refine the accountability system for food safety.

Software

The Outline of the People's Republic of China 15th Five-Year Plan for National Economic and Social Development states that the enhancement of computing power supply facilities and the full exploitation and use of data resources are encouraged in all areas, including medical care. Improvements in AI, data technologies and computing resources are expected to empower the development of medical software applications and push legislation to adapt.

Environmental Policy and Enforcement

The Ecological and Environmental Code of the People's Republic of China was adopted on 12 March 2026 at the Fourth Session of the 14th National People's Congress and shall formally enter into force on 15 August 2026; a series of standalone laws, such as those regulating water pollution, air pollution, soil pollution and environmental impact assessment, will be repealed simultaneously. Pharmaceutical enterprises and their subsidiaries may face administrative penalties for issues such as discharging wastewater, exhaust gases or solid wastes in excess of standards, or commencing work without EIA procedures, under more integrated and cohesive law enforcement.

5.2 Legislative Reform

Medical Devices

On 26 August 2024, the NMPA released the Medical Devices Administration Law of the PRC (Draft) for public comments. Compared to the RSAMD, the Medical Devices Administration Law has a higher tier of legal effect, elevating medical device regulation from an administrative regulation to a law.

For clinical trials, the NMPA promulgated the Inspection Points and Determination Principles for Medical Device Clinical Trial Projects in March 2025.

For quality management, the NMPA promulgated the Guidelines for On-Site Inspection of GSP for Medical Devices in July 2024, and the Announcement on Rewarding Internal Whistleblowers for Reporting Quality and Safety Violations of Drugs and Medical Devices in June 2025.

Human Genetic Resources

In 2024, the Administrative Regulations on Human Genetic Resources were revised and the Biosecurity Law of PRC amended, mainly changing the competent authorities for human genetic resources management; see **3.1 Regulatory Authorities**.

On 8 May 2026, the NHC released a new draft of the Implementing Rules for Human Genetic Resources Management, which is expected to replace the current Implementing Rules for the Administrative Regulations on Human Genetic Resources. The new draft revises core rules on collection approval, foreign entity identification and exempt samples. The public consultation closed on 7 June 2026, and the official version is expected to take effect within 2026.

Healthcare Products

On 26 June 2026, the NMPA issued the Provisions on the Administration of Registration and Filing Dossiers for New Cosmetic Ingredients, which streamlines classification criteria and dossier submission requirements for cosmetic new raw materials. The FSL (Amendment Draft) was released by the NPC Standing Committee for public comments and listed in the State Council's 2025 Legislative Work Plan.

5.3 Impact of Artificial Intelligence

Since 2016, China has enacted laws and policies encouraging the deep integration of AI and healthcare. AI has positively impacted drug R&D, medical devices, health management, internet healthcare and other fields by:

- saving new drug development time and trial-and-error costs;
- promoting a number of new medical imaging devices, medical robots and rehabilitation aids;
- providing intelligent solutions for daily health management and monitoring; and
- optimising the shortcomings of traditional internet healthcare in remote diagnosis and treatment.

The State Council's 2025 legislative work plan undertakes to advance legislation fostering the healthy development of AI. Although China has adopted targeted regulations on generative AI, foundational issues – eg, the legal nature of AI systems, governance architecture and allocation of liability – still require a comprehensive, high-level statute.

Released on 21 August 2025, the Opinions of the State Council on Deepening the Implementation of the "Artificial Intelligence+" Initiative set out national top-level AI strategies covering six core sectors, including people's health. It sets staged development targets up to 2035 and unified rules on AI risk control, ethical governance and supporting legislation, underpinning the subsequent healthcare-specific AI guidance issued by five central authorities.

To fill the gap in nationwide unified review standards for AI medical devices, the CMDE also released a draft of Guiding Principles for Clinical Evaluation and Registration Review of AI-Aided Diagnostic Medical Devices for public consultation on 10 June 2026.

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 AI and drug regulation.

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, they will be continuously updated as AI gives rise to new products and issues (as seen in the recent wave of medical AI software regulations), further enriching the current frameworks and increasing compliance obligations. Second, the basic concepts of the current frameworks may change: for example, how the subject qualification of medical robots is determined will decide whether they can be the subject of tort liability and ultimately affect the allocation thereof.

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