Medical Devices: Sources of Regulation in China

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A Practice Note explaining the regulatory regimes that apply to medical devices and their components in China. It covers both regulatory regimes specific to medical devices and general regulatory regimes that apply to a range of products including medical devices.

Medical devices are used extensively in healthcare systems globally to treat patients and, increasingly, to improve consumer health. There is normally a degree of risk associated with the use or misuse of medical devices. For this reason, most nations control and monitor the supply and use of medical devices. Additionally, due to the international nature of the medical device industry, many countries have formed relationships to facilitate cross-border trade in medical devices. This includes, for example, mutual recognition of conformity assessments and regulatory documents.

In **China (PRC)**, medical devices are subject to product-specific regulation. They are also subject to general product regulation that may apply to all product types or a subset of products, including medical devices or their components. This Note explains the regulatory regimes that may apply (depending on the exact nature of the medical device or component in question), what they seek to control, and the key legislation and sources of authoritative guidance.

Medical Devices

This section discusses the main product-specific regulatory regime that applies to medical devices, if any.

The *Regulations on the Supervision and Administration of Medical Devices 2021* (2021 Regulations on Medical Devices) sets the regulatory framework for the administration of medical devices, including in vitro diagnostic reagents (IVD). Under Chinese law, the term IVD includes not only products that relate to chemical agents but also products that do not relate primarily to chemical reactions including, for example, calibrators and reagent kits themselves.

The 2021 Regulations on Medical Devices and other detailed administrative measures and rules discussed in this Note apply to the development, registration, authorisation, manufacturing, distribution, and use of medical devices within China.

Development of Medical Devices

The development of medical devices is regulated by:

- The Research and Development of Products and Clinical Evaluation sections of the *Administrative Measures on the Registration and Record-filing of Medical Devices* and the *Administrative Measures on the Registration and Record-filing of IVD* (together, Registration and Record-Filing Measures).
- The *Measures for the Ethical Review of Biomedical Research Involving Humans 2016*.

Activities relating to clinical trials of medical devices are regulated by:

- The *Good Clinical Practice for Clinical Trials of Medical Devices* (Medical Device GCP). The last version of the Medical Device GCP was effective from 1 May 2022.

- The *Administrative Measures for Conditions and Record-filing of Clinical Trial Institutions of Medical Devices*.

The development of medical devices also must conform to a series of guidelines issued by Centre for Medical Device Evaluation under the *National Medical Products Administration* (NMPA).

Authorisation of Medical Devices

The Registration and Record-filing Measures require that medical devices, before they enter the market, are subject to either registration or record-filing based on their classification. Medical devices are categorised into three classes with different risk levels under the supervision of the NMPA and its local counterparts:

- Class I medical devices have a low degree of risk and are subject to record-filing administration only.

- Class II medical devices have a medium degree of risk. They must be registered.

- Class III medical devices have a high degree of risk. They must be registered.

(*Article 8, Administrative Measures on the Registration and Record-filing of Medical Devices*.)

Manufacturing of Medical Devices

The manufacturing of medical devices is regulated by:

- The *Measures for the Supervision and Administration of Medical Device Manufacture*.

- The *Good Manufacturing Practice for Medical Devices* (GMP) and its Appendices and Guidelines.

- Other mandatory national standards and industrial standards.

Distribution and Use of Medical Devices

The distribution of medical devices is regulated by the:

- The *Measures on Supervision and Administration of Business Operations of Medical Devices (2022)*.

- The *Good Supply Practice for Medical Devices* (GSP) and its Appendices and Guidelines.

- Other mandatory national standards and industrial standards.

- If the distributor engages in online distribution of medical devices, the *Measures for the Supervision and Administration of Online Sale of Medical Devices*.

The *Measures for the Supervision and Administration of Use Quality of Medical Devices* apply to the use of medical devices.

As a preliminary matter in medical device instructions, practitioners should consider whether the medical device in question qualifies as a regulated medical device under the applicable product-specific regulatory regime. For the US, UK, and EU context for making this determination, see *Practice Notes, Borderline considerations: medicinal products, medical devices, cosmetics and software* and *Identifying and Classifying Medical Devices: Overview*.

Under the Chinese legal regime, **medical device** means:

- Either:
    - instruments;
    - equipment;
    - appliances;
    - IVD;
    - calibrators; or
    - materials and other similar articles, including necessary computer software.

- 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 pharmaceuticals, medical devices achieve their utility mainly by physical or other means rather than pharmacological, immunological, or metabolic means. In medical devices, pharmacological, immunological, and metabolic means can only be auxiliary functions. (*Article 103, 2021 Regulations on Medical Devices*.)

Medical Devices and Pharmaceuticals

The Chinese legal regime categorises and regulates medical devices and pharmaceuticals as two different types of products. The only intersection of these two categories is combination products, which are medical products containing both pharmaceuticals (including Chinese medicine, chemical drugs, and biologic products) and medical devices (see *Advanced Therapies, Tissues, and Cells*).

Medical Devices and Cosmetics

Under the *Measures for the Supervision and Administration of Cosmetics Manufacturing and Operation 2021*, **cosmetics** refers to chemical and industrial products for daily use that are applied to the skin, hair, nails, lips, and other surfaces of the human body by smearing, spraying, or other similar methods for cleansing, protection, beautification, and dressing up. China has a cosmetic registration system that is separate from the medical device registration system.

The distinctions between medical devices and cosmetics in certain industries or product categories can be confusing for consumers. The most common area of confusion involves distinguishing surgical dressings used in cosmetology and aesthetic medicine institutes or similar scenarios from ordinary facial masks:

- **Surgical dressings** cannot use "mask" as their name, and surgical dressings cannot be used or claimed to be used for beauty or healthcare. A surgical dressing is classified as a medical device that can be used directly or indirectly on the surface of a wound with functions like wound healing or preventing medication from adhering.

- **Facial masks** are cosmetics. The NMPA has clarified on its website (see *NMPA: Safe use of makeup*) that facial masks are not subject to medical device registration or record-filing. Facial masks are only subject to cosmetic record-filing under the supervision of the NMPA and its local counterparts.

Cosmetics are divided into two main categories:

- **Special cosmetics** are cosmetics that claim certain special functions, for example, freckle removal, whitening, and sun protection, and are subject to cosmetic registration under NMPA supervision.

- **Ordinary cosmetics** are cosmetics other than special cosmetics. They are subject to cosmetic record-filing under the supervision of the NMPA and its local counterparts.

Cosmetics cannot claim any medical functions or effects (*Article 35, Measures for the Supervision and Administration of Production and Operation of Cosmetics 2021*).

Medical Devices and Software

Software is classified as a medical device if it meets the legal definition of a medical device (see *Distribution and Use of Medical Devices*). Medical device software can be divided into two main categories:

- Standalone software, which can be registered as an independent medical device.

- Software components, which should be registered with the medical device they work with.

For more information on medical device software and related issues, see *Software, Systems, Networks, and Cybersecurity*.

Chemicals

Some medical devices contain or are made using hazardous chemicals. In some regulatory regimes, a chemical itself may qualify as a medical device.

The laws and regulations applicable to hazardous chemicals are:

- The *Regulations on Safety Management of Hazardous Chemicals 2013* (2013 Chemicals Safety Regulations).
- The *Hazardous Chemicals Catalogue (2015 version)* (2015 Hazardous Chemicals Catalogue).
- The *Guidelines for Implementation of the Catalogue of Hazardous Chemicals (2015 edition)* (for Trial Implementation) and its appendix, the *Sheet of Classification Information of Hazardous Chemicals* (Hazardous Chemicals Guideline and Appendix).

The 2015 Hazardous Chemicals Catalogue and Hazardous Chemicals Guideline and Appendix are the basis for identifying whether a chemical is a hazardous chemical. If a chemical is identified as a hazardous chemical, it is subject to the following rules of the 2013 Chemicals Safety Regulations:

- **Prohibitions and restrictions on hazardous chemicals.** No individual or entity can:
  - produce, deal in, or use hazardous chemicals that are prohibited by the government; or
  - use hazardous chemicals in violation of restrictive provisions.
- **Safety production licence for hazardous chemicals.** Hazardous chemical production enterprises must obtain a safety production licence before starting production.
- **Safety use permit for hazardous chemicals.** Chemical enterprises (except for hazardous chemical production enterprises discussed in the bullet above) that use more than a specified amount of hazardous chemicals in their production must obtain a safety use permit for hazardous chemicals.
- **Operating licence for hazardous chemicals.** No individual or entity can engage in business operations using hazardous chemicals without an operating licence, with few exceptions. For example, hazardous chemical production enterprises and port operators are not required to obtain operating licences to sell hazardous chemicals within their factories or port areas.
- **Permit for transportation of hazardous chemicals.** An enterprise engaging in road transportation or waterway transportation of hazardous chemicals must obtain permits for road transportation or waterway transportation of dangerous goods and go through registration formalities with the competent Administration for Market Regulation.
- **Registration system for hazardous chemicals.** Hazardous chemical production enterprises or importers that produce or import the hazardous chemicals listed in the 2015 Hazardous Chemicals Catalogue must undergo registration procedures with the competent Emergency Management Authority in accordance with the *Administrative Measures for the Registration of Hazardous Chemicals*.

A medical device that uses hazardous chemicals must comply with the rules in the bullets above, including obtaining applicable licences or permits. For example, a medical device manufacturer that uses a prescribed amount of hazardous chemicals for production is considered a "chemical enterprise" and must obtain a safe use licence for hazardous chemicals. If a medical device manufacturer transports hazardous chemicals by road, it must obtain a road transportation licence for hazardous chemicals.

Radioactive Material

Some medical devices contain or are made using radioactive material or are otherwise used in connection with it. In some regulatory regimes, the radioactive material itself may qualify as a medical device.

The laws and regulations applicable to radioactive material are:

- The *Regulations on Safety and Protection of Radioisotopes and Radioactive Devices 2005* (2005 Regulations on Radioactive Materials).
- The *Administrative Measures for Safety Licence of Radioisotopes and Radiation Devices* (Safety Licence Measures).
- The *Administrative Measures for the Occupational Health Management of Radiation Workers* (Measures on Radiation Workers).

The 2005 Regulations on Radioactive Materials and the Safety Licence Measures apply to the manufacture, sale, and use of radioisotopes and radioactive devices and to the transfer and import and export of radioisotopes within Chinese territory, and they require parties to obtain licences and permits for these activities. The Measures on Radiation Workers apply to entities and radiation workers (including medical institutions and their medical staff) that engage in activities related to radioisotopes, radioactive devices, and other regulated radioactive materials.

In the medical device industry, radioactive materials are mostly used in radiotherapy devices and medical imaging devices. They are also used in medical diagnostic and monitoring devices, physical therapy devices, medical disinfection and sterilisation devices, and so on. Most of these medical devices are Class II and Class III medical devices (see *Authorisation of Medical Devices*).

Medical institutions that engage in radiodiagnosis and radiotherapy (including using radioisotopes and radioactive devices to carry out activities like clinical diagnosis, treatment, and physical examination) must comply with the *Administrative Provisions on Radiodiagnosis and Radiotherapy*.

Advanced Therapies, Tissues, and Cells

Modern medicine uses cutting-edge combinations of medical devices with pharmaceuticals, tissues, cells, and other materials. Those products may fall under a particular regulatory regime or be subject to multiple regulatory regimes that apply to the different parts of the product.

The *Measures on the Administration of Drug Registration 2020* and the *Registration Classification and Requirements for Application Dossiers for Biological Products* specify that biologically active products extracted from tissues, cell therapy, and gene therapy products are classified as biological products and regulated by the pharmaceutical regulations. Therefore, cell therapy or gene therapy products can be combined with medical devices and form combination products. A **combination product** involving a medical device is a medical product that:

- Consists of both a pharmaceutical and a medical device.
- Is produced as a single product.

(*Announcement on Issues Relating to Registration of Drug-Medical Device Combination Products (Circular No 52 of 2021)*.)

A combination product is categorised as either a pharmaceutical or a medical device depending on its main functions. If a combination product's function mainly relies on the effective mechanism of a pharmaceutical, it should be registered as a pharmaceutical. If a combination product's function mainly relies on the effective mechanism of a medical device, it should be registered or record-filed as a medical device. Current Chinese law does not offer further guidance in identifying when a product "mainly relies" on a certain mechanism. If identifying the combination product's main function is difficult, the applicant should apply to the NMPA's Centre for Medical Device Standardisation Administration to identify the main function of the combination product before applying for registration or record-filing. (See *Announcement on Issues Relating to Registration of Drug-Device Combination Products (Circular No 52 of 2021)*.)

If a combination product is registered as a pharmaceutical, the relevant laws and regulations on pharmaceuticals apply. If a combination product is registered as a medical device, it is regulated as a Class III medical device (see *Authorisation of Medical Devices*).

Machinery and Equipment

Within the general description of medical devices, there are many types of laboratory and clinical equipment. Equipment may be regulated either as a medical device under the applicable product-specific regime, under separate equipment regulatory regimes, or both.

Generally, equipment or measuring devices and electrical equipment are classified and regulated as medical devices if they meet the legal definition of a medical device (see *Distribution and Use of Medical Devices*). Specifically, to determine whether electrical equipment or a measuring device is a medical device, a party can refer to the *Classification Catalogue of Medical Devices (2017) (as periodically amended)* (2017 Medical Device Catalogue) or apply to the NMPA's Centre for Medical Device Standardisation Administration.

Specific regulatory requirements for certain types of equipment are:

- **Large medical equipment.** Pieces of large medical equipment are classified as medical devices. Large medical equipment means large medical devices that use complex technology, require large capital investment, have high operating costs, have a great impact on medical expenses, and are included in the *Catalogue of Large Medical Equipment* issued by the *National Health Commission*. Large medical equipment is regulated mainly by the *Administrative Measures for the Allocation and Use of Large Medical Equipment*. Large medical equipment is divided into two categories:
  - for category A large medical equipment, the user must apply to the National Health Commission for a licence; and
  - for category B large medical equipment, the user must apply to the provincial Health Commission for a licence.

- **Medical electrical equipment.** This is a kind of electrical equipment used in diagnosis, treatment, and monitoring of patients that is classified as a medical device. Medical electrical equipment must conform to mandatory national standards and industrial standards, including GC 9706.1-2020 (*Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*) and YY 0505-2005 (*Medical Electrical Equipment Part 1: General Requirements for Safety - Collateral Standards: the Requirements for Electromagnetic Compatibility and Tests*).

- **Electronic products.** Electronic products that are classified as medical devices are regulated by both regulations of medical devices (see *Medical Devices*) and regulations of electronic products, for example, the *Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products*.

Consumer Protection, General Safety, and Product Liability

Medical devices, if defective or used improperly, may cause injury or damage to property.

If medical devices cause any injury or damage to any person or property, liability for compensation is governed by the *Regulation for the Supervision and Administration of Medical Devices* and the *Civil Code of the PRC 2020* (2020 Civil Code, with effect from 1 January 2021).

Contractual and Tort Liability

In China, product liability can be divided into two main categories: contractual liability and tort liability.

For contractual liability, the general principle is that, where any party fails to perform its obligations under a contract or its performance fails to satisfy the terms of the contract, the party bears liability for breach of contract, for example by taking remedial measures or compensating for losses (*Article 577, 2020 Civil Code*).

For tort liability relating to products, the 2020 Civil Code provides that the manufacturer or distributor bears strict liability for product defects that have caused damage to others. In other words, in product liability claims, the plaintiff only needs to prove that:

- The product has defects.

- Damage occurred to the plaintiff.

- There is a causal relationship between product defects and damage.

The plaintiff does not have to prove the defendant's intent or negligence of the defendant (that is, the manufacturer or the distributor) (*Article 1202 and 1203, 2020 Civil Code*.)

A manufacturer is not liable if it proves one of the following:

- The product has not been put into circulation.

- The defect causing the damage did not exist when the product was put into circulation.

- When the product was put into circulation, the level of science and technology at the time was not sufficient to detect the existence of the defect.

(Article 41, *Product Quality Law of the PRC 2018* (2018 Product Quality Law).)

When contractual liability and tort liability occur together under the same legal facts, that is, where one party breaches an agreement and causes damage to the other party's personal or property rights and interests, the damaged party has the right to request that the defendant assume either contractual liability or tort liability (*Article 186, 2020 Civil Code*).

Liability for Medical Malpractice

If a patient suffers damage because of a defective medical device, the patient can claim compensation from any of:

- The medical device registration or record-filing holder.
- The manufacturer of the medical device.
- The medical institution.

If the patient claims compensation from the medical institution, the medical institution has the right to recover the amount of compensation it pays to the patient from either:

- The responsible medical device registration or record-filing holder.
- The manufacturer of the medical device.

(*Article 1223, 2020 Civil Code*; *NMPA: How to compensate for damages caused by medical devices*.).

Health Systems and Public Procurement

Medical devices, as healthcare products, are often supplied to a country's national health system in a particular way, and the price that is paid or reimbursed for medical devices may be subject to controls.

The major procurement modes of medical devices (including medical equipment and medical consumables) in China include national or regional centralised procurement, regional joint procurement, and other procurement of medical devices through online procurement platforms set up by authorities. Medical device manufacturers need to arrange for the bidding in accordance with applicable procurement catalogues and the requirements of various procurement policies corresponding to different procurement modes. Generally, domestic and foreign suppliers can participate in procurement under the same requirements and through the same processes, though some exceptions exist. For example, in recent years, China has encouraged the purchase of locally made large-scale medical equipment, especially by public hospitals.

Generally, the public medical institutions and non-profit medical institutions set up by governments (at all levels) or by state-owned enterprises must participate in centralised procurement organised by national or regional authorities. Other medical institutions

are also encouraged to participate in this centralised procurement. However, to date there is no official information or data available regarding other institutions' participation in centralised procurement.

Typical national or regional centralised procurement includes:

- **Centralised procurement of large medical equipment.** For non-profit medical institutions set up by governments at all levels and state-owned enterprises:
    - the National Health Commission organises centralised procurement of category A large medical equipment (governed by the Regulation for Centralised Procurement of Category A Large Medical Equipment (for Trial Implementation)); and
    - provincial Health Commissions organise centralised procurement of category B large medical equipment.

  For more information on large medical equipment, see *Machinery and Equipment*.

- **Centralised procurement of high-value medical consumables.** National medical insurance authorities, coordinating with other competent authorities, organise the national centralised procurement of certain high-value medical consumables by public medical institutions. This process has included, for example, certain coronary stent and joint prosthesis products.

Online procurement platforms and the scope of medical devices included on them are generally subject to regulations or requirements issued by provincial or city-level authorities that establish the platforms.

Dual Use and Export Restrictions

Medical devices, their components, or their incorporated technology may be used for illicit purposes such as terrorism, warfare, illegal surveillance, or cyberattacks. For this reason, some nations may have a system designed to prevent undesired use of materials contrary to that nation's security interests.

The laws and regulations that restrict the export of goods and technologies, including dual use items and technologies, are:

- The *Foreign Trade Law of the PRC 2020 (*2020 Foreign Trade Law).
- The *Administrative Regulations of the PRC on Import and Export of Technologies*.
- The *Administrative Regulations of the PRC on the Import and Export of Goods 2001* (2001 Goods Import and Export Regulations, with effect from 1 January 2002).
- The *Export Control Law of the PRC 2020*.
- The *Administrative Measures for the Import and Export Authorisation of Dual-Use Items and Technology*.
- The *Catalogue of Technologies Prohibited or Restricted from Export by the PRC* (Technologies Control List).

- The *Catalogue of Goods Prohibited from Export by the PRC* (Goods Prohibited List).
- The *Catalogue for the Administration of Export Authorisation for Goods* (Goods Control List).
- The *Catalogue for the Administration of Import and Export Authorisation for Dual Use Items and Technologies* (Dual Use Control List).

Export Restrictions on Certain Goods or Technologies

If a medical device or its components are listed in the Goods Prohibited List, or if its incorporated technologies fall under the Technologies Control List as being prohibited from export, the medical device may be prohibited from export.

If a medical device or its components are listed in the Goods Control List, or if its incorporated technologies fall under the Technologies Control List as being restricted from export, the medical device requires prior approval before export.

Export Restrictions on Dual Use Items and Technologies

If a medical device or its components or its incorporated technologies are listed in the Dual Use Control List, the competent provincial Commerce Bureau must examine and approve export of the medical device before export.

Software, Systems, Networks, and Cybersecurity

Many medical devices contain software and networking hardware and are linked to networks so they can be monitored and controlled remotely. This may include the transfer of data concerning the patient or consumer.

The laws and regulations that apply to medical devices that contain software and networking hardware and are linked to networks are:

- The *Cybersecurity Law of the PRC 2016* (2016 CSL, effective from 1 June 2017).
- The *Data Security Law of the PRC 2021* (2021 DSL).
- The *Personal Information Protection Law of the PRC 2021* (2021 PIPL).
- The *Administrative Measures on Standards, Security, and Service of National Health Big Data 2018*.
- The *Technical Review Guideline on Medical Device Software Registration*.
- The *Technical Review Guideline on Network Security Registration of Medical Devices*.
- The *Technical Review Guideline on Mobile Medical Device Registration*.

Chinese law classifies some medical device software as medical devices. Medical device software is divided into two main categories:

- **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. Some standalone software is registered as a medical device.

- **Software component** refers to software intended to be used for one or more medical purposes that controls or drives a hardware medical device or runs on a dedicated or medical computing platform. A software component is a component of a medical device and should be registered with the medical device it works with.

(*Section 1, Technical Review Guideline on Medical Device Software Registration*.)

Mobile medical devices either contain standalone software or are themselves standalone software (*section 2, Technical Review Guideline on Mobile Medical Device Registration*).

In current practice, medical devices that contain software and are linked to networks face network security threats. Network security threats, for example, invasion of patients' privacy through data leakage or unpredictable operational issues can result in serious injury or even death to patients and users. Therefore, Chinese law regulates cybersecurity and data security strictly. The registration applicant of medical devices that contain software must assess the network security features of the medical device based on the expected use, usage environment, and core functions to ensure the network security of the medical device, and submit a network security description document. However, there is currently no generally applicable safety standard for medical devices containing software. Rather, security should be completed with reference to relevant international and national standards and technical reports.

Cybersecurity

The party that holds the market authorisation for registered or record-filed medical devices that are linked to networks must:

- Pay continuous attention to network security issues during the entire life cycle of the medical devices.

- Comply with a user-notification obligation regarding medical device network security.

- Maintain the confidentiality, integrity, and availability of relevant medical data.

(*Section 2, Technical Review Guideline on Network Security Registration of Medical Devices*.)

Data Security

One of the important aspects of data security is the protection of personal information. **Personal information** refers to any kind of information related to an identified or identifiable natural person as recorded electronically or otherwise, excluding information that has been anonymised. **Personal information processor** refers to any organisation or individual that independently determines the purpose and method for processing personal information. Personal information processors are responsible for their activities in processing personal information (including collection, storage, use, processing, transmission, provision, disclosure, and

deletion of personal information) and must take necessary measures to ensure the security of the personal information they have processed. (*Article 4, 2021 PIPL*.)

If a personal information processor collects or otherwise processes the personal information of patients through medical devices or otherwise, the personal information processor must obtain the personal consent of the patients and inform them of:

- The name and contact information of the personal information processor.
- The purpose and method of processing.
- The type of personal information to be processed.
- Other matters required by law.

If the personal information to be collected includes sensitive personal information (for example, biometric recognition and medical and health information), the personal information processor must also obtain specific consent from the patients and inform them of the processing of sensitive personal information and the impact on the patient's rights and interests. The cross-border transfer of personal information must comply with specific requirements, for example, security evaluation by the *Cyberspace Administration of China*. (*Articles 13, 17, 30, and 38, 2021 PIPL*.)

If personal information processing involves Chinese human genetic resources, the collection, preservation, use, and cross-border transfer must comply with the *Biosafety Law* and the *Regulations on Administration of Human Genetic Resources 2019* (2019 HGR Regulations).

If the personal information processing involves **healthcare big data**, that is, healthcare data generated in the course of disease prevention, treatment and health management, the processing also must comply with the *Administrative Measures on Standards, Security, and Service of National Health Big Data*.

Packaging and Labelling

In some jurisdictions, there is a product-specific medical device regulatory regime, which may include certain requirements on packaging and labelling. However, other jurisdictions have general regulatory regimes that determine the packaging in which a manufacturer needs to put its product and the information it must provide on the outside of the product or packaging.

The Chinese laws and regulations applicable to packaging and labelling of medical devices are:

- The 2021 Regulations on Medical Devices.
- The *Administrative Rules on Instruction Manuals and Labels of Medical Devices*.
- The *Rules on the Unique Identification System for Medical Devices.*

When a party applies to the NMPA or its local counterpart for registration or record-filing of a medical device, the party must submit the device's instruction manuals and labels.

Instruction Manuals

The **instruction manual** of a medical device refers to technical documents created by the holder of the medical device's registration or record-filing that are provided to users with the medical device and that cover basic information on the safety and effectiveness of the medical device. The NMPA or its local counterpart must approve or record the instruction manual of a medical device.

The content of the instruction manual of a medical device must meet certain requirements. The instruction manual must contain, among other things:

- The name, model, and specification of the medical device.
- The registration or record filing information.
- Information about the manufacturer.
- Certain warnings and reminders.

The instruction manual cannot include assertions or guarantees, for example best efficacy or ensured cure, and it cannot contain absolute descriptions like the highest technology, the best, and so on. (*Article 39, 2021 Regulations on Medical Devices; Articles 10, 11, and 14, Administrative Rules on Instruction Manuals and Labels of Medical Devices*.)

Labels

The **label** of a medical device refers to the written descriptions, graphics, and symbols that are attached to the medical device or its packaging and that are used to identify the device's features and to indicate safety warnings. The rules for the content on labels of medical devices are similar to the rules for the content of instruction manuals (see *Instruction Manuals*). (*Article 39, 2021 Regulations on Medical Devices; Articles 3, 13, and 14, Administrative Rules on Instruction Manuals and Labels of Medical Devices*.)

Unique Identification System

The **unique identification** of a medical device refers to a code composed of numbers, letters, or symbols that is attached to the medical device or its packaging. The holder of a medical device's registration or record-filing of medical devices is responsible for:

- Creating and maintaining unique identification.
- Attaching the unique identification data carrier for the medical device to the medical device or its packaging.
- Uploading relevant data.
- Strengthening the whole process of managing medical devices through the use of the unique identification system.

(*Articles 3 and 6, Rules on the Unique Identification System for Medical Devices*.)

Advertising and Promotion

In some jurisdictions, there is a product-specific medical device regulatory regime which may include certain requirements on advertising and promotion activities relating to medical devices. There may also be a general regulatory regime, which may include industry self-regulation, to ensure that businesses adopt fair practices in selling their products.

The Chinese laws and regulations applicable to advertising and promotion activities are:

- The *Advertising Law of the PRC 2021* (2021 Advertising Law).
- The *Interim Administrative Measures for Examination of Advertisements for Drugs, Medical Devices, Health Foods, and Formula Foods for Special Medical Purposes* (Interim Measures on Advertisements).
- The *Measures for the Administration of Internet Advertising 2023*.
- The *Anti-Unfair Competition Law of the PRC 2019* (2019 AUCL).

The *Compliance Management Specification for Pharmaceutical Industry* (PIAC/T 00001-2020) issued by the China Pharmaceutical Industry Association is also a reference for compliance requirements regarding advertising and promotion activities for medical devices.

Advertising of Medical Devices

Generally, any activity and behaviour on certain media (including internet websites, television, radio, newspapers, and magazines) that directly or indirectly introduces or recommends a medical device may constitute advertising (*Article 2, 2021 Advertising Law*).

Prohibitions on advertising medical devices include:

- Medical devices that are used for addiction treatment (*Article 15, 2021 Advertising Law*).
- Medical devices that cannot be produced, sold, or used also cannot be advertised (*Article 37, 2021 Advertising Law*).
- Medical device advertising cannot be published in public media that targets minors (*Article 40, 2021 Advertising Law*).

The advertising of medical devices is subject to prior examination and approval by the relevant local authorities under the State Administration for Market Regulation. The advertiser must obtain a unique approval number for advertising the medical device and clearly indicate this number in the advertising (*Article 46, 2021 Advertising Law*).

Generally, all the content of a medical device advertisement must be true and lawful and cannot contain any false or misleading content. Advertisers are responsible for the veracity and legitimacy of the content. The content also must comply with the device's

registration certificate or filing certificate and with the instruction manuals as approved by competent authorities (*Articles 3 to 6, Interim Measures on Advertisements*).

Online advertising of medical devices also must comply with the Measures for the Administration of Internet Advertising. For example, internet advertising must be identifiable as advertising and clearly marked as "advertisement" to ensure that consumers can identify it as an advertisement. Paid-for advertisements within search results must be clearly distinguished from natural research results, and internet advertising must not affect the normal use of the internet by users (*Article 9, Measures for the Administration of Internet Advertising*).

Promotion Activities Other Than Advertising

Promotion activities other than advertising, for example holding academic conferences and lectures, must comply with the 2019 AUCL. For example, the party engaging in these activities cannot make any false or misleading promotions to defraud or mislead consumers or violate any anti-bribery and anti-corruption regulations.

All advertising and promotion activities also must comply with the *Trademark Law of the PRC 2019* (2019 Trademark Law), *Copyright Law of the PRC 2020* (2020 Copyright Law, with effect from 1 June 2021), and *Patent Law of the PRC 2020* (2020 Patent Law, with effect from 1 June 2021). For example, a party cannot use another party's copyrights without prior permission, and a party cannot present an unregistered trademark as registered in advertising and promotion activities.

Waste and Environmental

Used medical devices and the by-products of their manufacture may be regulated types of waste and could pose risks to the environment and human health.

The main laws and regulations regarding environmental protection applicable to the manufacturing of medical devices or disposal of used medical devices in China are:

- The *Environmental Protection Law 2014* (2014 Environmental Protection Law, with effect from 1 January 2015).
- The *Solid Waste Pollution Prevention and Control Law 2020* (2020 Solid Waste Pollution Law).
- The *Measures for the Transfer of Hazardous Wastes*.
- The *Regulations on the Administration of Pollutant Discharge Permits*.
- The *Regulations on Management of Medical Wastes 2011* (2011 Medical Waste Regulations).
- The *Measures of Medical Waste Management for Medical Institutions*.

Environmental Protection Requirements Regarding Manufacturing Medical Devices

The main types of pollution caused by the manufacturing of medical devices include air pollution, water pollution, and solid and hazardous waste.

Before constructing a factory for the manufacturing of medical devices, a party must prepare environmental impact reports or registration forms and have them approved by competent environment protection authorities.

As to air and water pollution during the manufacturing of medical devices, the manufacturer must obtain pollutant discharge permits.

The collection, storage, transfer, use, and disposal of solid and hazardous waste must comply with the 2020 Solid Waste Pollution Law. For example, the transfer of hazardous waste between provinces must be approved by provincial environment protection authorities.

Environmental Protection Requirements Regarding Medical Institutions' Disposal of Used Medical Devices

When disposing of medical waste, including medical devices, medical institutions must comply with requirements set out in the laws and regulations, including those in the Measures of Medical Waste Management for Medical Institutions, 2011 Medical Waste Regulations, and the 2020 Solid Waste Pollution Law. For example, under the Measures of Medical Waste Management for Medical Institutions, medical institutions must collect medical waste by category and transfer it to the entities approved by authorities for concentrated disposal of medical waste.

