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China

LIFE SCIENCES

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in China.

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1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

a) Medicinal Products

The *Drug Administration Law* is the cornerstone of medical product regulations in China, which encompasses a wide range of regulatory requirements, including drug research and development, registration, manufacturing, distribution, use, post-market pharmacovigilance, pricing and advertising, together with drug reserve and supply. The relevant authorities also enact detailed ordinances and regulations to facilitate the implementation of the *Drug Administration Law*.

Different categories of medical products are regulated under separate legislations. For instance, traditional Chinese medicine is governed by the *Traditional Chinese Medicine Law*, while vaccines, being specialized large-molecule biologicals, are regulated under the *Vaccine Administration Law*.

b) Medical Devices

The *Regulation on the Supervision and Administration of Medical Devices* governs the registration and filing, production, manufacturing, and use of medical devices, as well as the handling of adverse events and recall of medical devices. Medical devices are regulated with three classified categories based on the principles of risk management, with each category subject to varying requirements for testing, clinical evaluation, and quality management systems.

c) Food and Food Supplements

Food quality and safety in China are overseen by the *Food Safety Law* and its accompanying implementing rules. This law provides the framework for managing various aspects of food products, encompassing production, distribution, recall, and trading. Specific regulations are in place to further reinforce food safety at different stages for food production, trading, import and export, etc.

Food Supplements, also known as healthcare food, is a special food further regulated by the *Administrative Measures for the Registration and Filing of Healthcare Food* which outlines the procedures for registering and recording healthcare food products in China.

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

The regulatory process covers every stage of the entire life cycle of medicinal products and medical devices, which mainly includes pre-clinical and clinical studies, registration, manufacturing, distribution, and post-marketing regulation. The regulatory framework for the entire life cycle is governed by a combination of overarching laws, regulations, guidelines and policies, as well as more specific legislations, guidelines and policies that apply to each individual stage of the product life cycle.

Specifically, major rules include

a) General rules relating to the entire regulatory process:

• *Drug Administration Law*

• *Regulations for the Implementation of the Drug Administration Law*

• *Regulations for the Supervision and Administration of Medical Devices*

b) Specific rules relating to pre-clinical and clinical study

• *Regulations for the Administration of Affairs*

Concerning Experimental Animals

• *Good Laboratory Practice for Drugs*

• *Good Clinical Practice for Drugs*

• *Good Clinical Practice for Medical Devices*

c) Specific rules relating to registration

• *Provisions for Drug Registration*

• *Provisions for Medical Device Registration and Filing*

• *Provisions for In-vitro Diagnostic Reagent Registration and Filing*

d) Specific rules relating to manufacturing

• *Provisions for the Supervision and Administration of Drug Manufacturing*

• *Good Manufacturing Practice for Drugs*

• *Provisions for Supervision and Administration of Medical Device Manufacturing*

• *Good Manufacturing Practice for Medical Devices*

e) Specific rules relating to distribution

• *Provisions for Quality Supervision and Administration of Drug Distribution and Use*

• *Good Supply Practice for Drugs*

• *Provisions for Supervision and Administration of Medical Device Distribution*

• *Good Supply Practice for Medical Devices*

f) Specific rules relating to post-marketing regulation

• *Good Vigilance Practice for Drugs*

• *Provisions for Administration of Drug Recall*

• *Provisions for Adverse Drug Reaction Reporting and Monitoring*

• *Provisions for Medical Device Adverse Event Monitoring and Re-evaluation*

• *Provisions for Administration of Medical Device Recall*

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

a) Overview of Life-cycle Regulatory Requirements for Food Supplements

- **Registration/Filing**: Food supplements using raw materials not included in the *Food Supplements Raw Materials Directory* or first-time imported food supplements (except for vitamins, minerals and other nutrients) shall be registered with the State Administration for Market Regulation (the "SAMR"), while other food supplements (including vitamins, minerals and other nutrients) shall be filed with the local Administration of Market Regulation (the "AMR").
- **Manufacture:** Manufacturers of food supplements are required to obtain production license, maintain a quality management system in consistent with GMP, conduct regular self-inspection and submit self-inspection reports to the local AMR.
- **Sales and Marketing**: Sellers of food supplements need to complete record-filing with the local AMR and strictly adhere to advertisement requirements prescribed by applicable laws and regulations. Advertisements of food supplements claiming functions of disease prevention or treatment are prohibited.
- **Post-marketing Supervision**: All unsafe food supplements shall be recalled, and remedial measures (such as hazard-free disposal or destruction) shall be taken to mitigate any adverse effects.

b) Regulations Applicable to Food in General

- *Food Safety Law*
- *Implementing Regulation for the Food Safety Law*
- *Administrative Measures for Food Production Licensing*
- *Administrative Measures for Food Operation Licensing and Record-filing*
- *Administrative Measure for Food Recalls*

c) Regulations Specifically Applicable to Food Supplements

- *Administrative Measures for the Registration and Filing of Healthcare Food*

- *Administrative Measures for the Healthcare Food Raw Materials Directory and Health Functions Directory Allowed to be Claimed by Healthcare Food*
- *Healthcare Food Registration Review Rules*
- *Rules for the Review of Healthcare Food Production License*
- *Interim Administrative Measures for the Examination and Administration of Advertisements for Medical Products, Medical Devices, Healthcare Food and Formula Food for Special Medical purposes*
- *Implementing Rules for Technical Assessment of New Functions and Products of Healthcare Food (for Trial Implementation)*

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

In China, the post-marketing obligations of the market authorization holders of medicinal products and the holders of registration /record filing of medical devices are similar under the relevant regulations, which mainly include:

a) Establishing post-marketing risk management plans and proactively conducting post-marketing studies on the products/devices;

b) For those products/devices approved under conditions, completing further studies and submitting relevant information to the authority timely as required to obtain regular approvals;

c) Completing the applicable change procedures (including approvals, filings and reporting) in case of minor or major changes to the products/devices;

d) Monitoring and reporting adverse reactions/events and taking appropriate measures to control the risks;

e) Conducting product recall in the event that the medicinal products have quality problems or other safety issues, or the medical devices have defects, as applicable; and

f) Conducting post-marketing evaluations regarding the safety, efficacy and quality of the products/devices.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

In China, the National Medical Products Administration (the "NMPA"), formerly known as the China Food and Drug Administration (CFDA), is the primary regulatory authority for medicinal products, including pharmaceuticals and biologicals. Its responsibilities include drug approvals, registration, inspections, post-market surveillance, and the enforcement of regulations related to drug safety, efficacy and quality. The NMPA also regulates clinical trials, pharmacovigilance, and the import and export of medicinal products.

The SAMR is a regulatory authority overseeing various sectors, including food and food supplements. The responsibilities of the SAMR include the formulation and enforcement of food safety regulations, monitoring of food production and circulation, inspection and supervision of food quality, and the handling of food-related complaints and emergencies. The SAMR oversees compliance with the *Food Safety Law* and sets standards for labelling, additives, contaminants, and nutritional claims on food and food supplements.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

In China, the procedure for challenging regulatory decisions, such as the denial of marketing authorization, varies based on the specific product category, such as medicinal products, medical devices, or food supplements.

Generally, the first step to challenge regulatory decisions is to file an administrative reconsideration request with the same regulatory authority that made the initial decision. For example, if a market authorization has been denied, the request shall be filed with the Center for Drug Evaluation (the "CDE") for drugs, or the Center for Medical Device Evaluation (CMDE) for medical devices. The relevant regulatory authority will review the decision and supporting documents, and may conduct additional investigations if necessary. A reconsideration decision will then be issued, either upholding or modifying the initial decision.

If the administrative reconsideration decision does not provide a satisfactory outcome, the next step is to file an

administrative lawsuit with the court. The court will then issue a judgment either affirming or overturning the regulatory decision.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

In China, clinical trials for medicinal products (unless exempted by laws) are subject to the approvals from the NMPA in accordance with the *Drug Administration Law* and shall satisfy the requirements in the above-mentioned laws and regulations, and guidelines issued by regulatory authorities regarding technical requirements, regulatory procedures and inspections, etc. Prior to initiating clinical trials, the sponsor may apply for a formal meeting with the CDE and then submit an application for such trial after the meeting. The CDE will make a formal review. If the sponsor receives a notice of approval or receives no objection or only supplementary requirements from the CDE within a 60-day period after the acceptance of the application, approval would be deemed to be granted, and the sponsor is permitted to proceed with the clinical trial. In case of a denial, the sponsor may submit written replies and reapplications after making the necessary corrections. The CDE will reply to the reapplication within a 60-day period after receiving the reapplication. The sponsor can only proceed with trials after receiving the CDE's approval of the reapplication.

The regulations for clinical trials between medical devices and medicinal products exhibit significant difference. Unlike medicinal products, which are subject to clinical trials in principle, not all medical devices need to conduct clinical trials. While Class I medical devices and certain Classes II and III medical devices listed in a catalog issued by the NMPA are exempt from clinical evaluation, other Classes II and III medical devices are required to undergo clinical evaluations before registrations or filings (except those expressly exempted by the NMPA). Clinical trials for medical devices, as a method of clinical evaluation, are necessary only when the analysis of clinical literature and existing clinical data are insufficient to confirm safety and efficacy of the devices. When applying for clinical trials for medical devices, the process is generally regulated through a filing system at the provincial-level authorities. However, for medical devices listed in a catalog issued by the NMPA, clinical trials require the NMPA's approval. The approval process of clinical trials for medical devices follows a similar implied approval system as that for medicinal products.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Yes, the CDE has a Drug Clinical Trial Registry and Information Disclosure Platform (http://www.chinadrugtrials.org.cn) (the "CDE Platform"), which serves as the public database for drug clinical trials.

The *Provisions for Drug Registration* provide that, before carrying out clinical trials, sponsors shall submit the protocols and other information on the CDE Platform. During the clinical trials, sponsors shall continually update the information. After the end of the clinical trials, sponsors shall submit the results and other related information. Information posted on the CDE Platform will be disclosed to the public. The sponsors are responsible for the authenticity of such information. In addition to such general rules, the CDE has also published the *Regulation for Drug Clinical Trial Registry and Information Disclosure (Trial)*, which sets out more detailed requirements for clinical trial information publication.

Moreover, China also has the Chinese Clinical Trial Registry (the "ChiCTR") serving as a public database for clinical trials of drugs and medical devices, which is one of the WHO ICTRP primary registries. The ChiCTR publishes on its website (https://www.chictr.org.cn/guide.html) the rules for publication.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

In China, the usage of clinical trial data is strictly regulated to ensure the safety and efficacy of drugs, medical devices, and other healthcare products. The regulations require data integrity, obtaining informed consent from participants, ethical review by ethics committees, and compliance with the *Good Clinical Practice* (GCP) guidelines, etc.

In terms of privacy protection, the *Personal Information Protection Law* categorizes medical health information as sensitive personal information and mandates requirements, such as separate consent, for its processing. Stringent safeguards are also needed to be

put in place to prevent leakage or misuse of clinical data as personal information.

For cross-border co-development or multi-center clinical trials, the Cyberspace Administration of China (the "CAC") has issued cross-border data transfer rules that require specific safeguards, such as undergoing a security assessment approved by the CAC or executing standard contract clauses and filing them with local CAC authorities.

If clinical trial data involves human genetic resource information, additional regulatory obligations must be met in accordance with the *Administrative Regulations on Human Genetic Resource*s and its implementation rules. These may include obtaining approval from or filing with the China National Center for Biotechnology Development.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

In China, there has been remarkable progress in the digitization of clinical trials in recent years. Regarding the application process, following the 2019 *Announcements on Implementing Electronic Application for Medical Device Registration* and 2022 *Announcements on Implementing Electronic Application for Drug Registration* by the NMPA, the clinical trial application for Class III high-risk medical devices and drug clinical trial applications are now submitted electronically. Clinical trial filings for other medical devices, which fall under the oversight of provincial authorities, are also mostly open to electronic submissions.

Regarding the conduction of clinical trials, the industry is actively exploring the implementation of Decentralized Clinical Trials ("DCT"), driven by the development of digital technology and telemedicine. This exploration encompasses various facets, such as electronic informed consent, remote follow-up, and the formulation and publication of expert consensus. For instance, in 2022, an expert consensus outlining the conduction of remote intelligent clinical trials was released, offering valuable insights for navigating DCT compliance in China.

The regulatory authorities also recognize and support the industry's earnest exploration of DCT. On July 27, 2023, the CDE released the *Technical Guidelines for the Implementation of Patient-Centred Drug Clinical Trials (for Trial Implementation)*, offering significant guidance for the compliant implementation of DCT from the regulatory perspective. (for further interpretation, please refer to: China DCT Regulation and Implementation)

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

a) Medicinal Products & Medical Devices

According to the *Drug Administration Law*, a Marketing Authorization Holder ("MAH") is a company or drug research institution which has obtained a drug registration certificate from the NMPA. Individuals are not yet legally permitted to be MAHs. The MAH may either manufacture the medicinal products or medical devices (as applicable) itself or engage a contract manufacturing organization ("CMO") to manufacture.

With respect to medicinal products, the MAH manufacturing the medicinal products shall obtain an A-Class regulatory approval for manufacturing. In the case of the MAH engaging a CMO to manufacture medicinal products, the MAH shall obtain a B-Class regulatory approval for manufacturing and such CMO shall obtain a C-Class regulatory approval for manufacturing.

With respect to medical devices, legal requirements are different for each class of medical devices. For Class I medical devices, the MAH and the CMO shall file with the NMPA's competent municipal counterparts before manufacturing such devices. For Class II and Class III medical devices, the MAH and the CMO shall obtain regulatory approvals from the NMPA's provincial counterparts. Additionally, high-risk implantable medical devices shall not be manufactured by a CMO under the PRC law.

b) Food and Food Supplements

Food or food supplements must be produced by a manufacturer with regulatory approval for food manufacturing. If an MAH intends to engage a CMO to manufacture the food or food supplements, the CMO needs to obtain a regulatory approval for food manufacturing, and shall conduct the manufacturing activities under the supervision of the MAH. In addition, according to a draft guideline circulated recently, the MAH and the CMO may be required to file with the relevant local counterparts of the SAMR regarding CMO arrangements in the future.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

a) Medicinal Products & Medical Devices

Distributor. For medicinal products, an entity that has obtained the regulatory approval for medicinal products business operation is eligible to distribute medicinal products. For medical devices, Class I medical devices can be distributed by any entity without any requirements of filing or regulatory approval. Class II medical devices shall only be distributed by entities that have filed with the NMPA's municipal counterparts. Class III medical devices can be distributed by entities with regulatory approvals for operating medicinal devices.

Distribution Process. The distribution process for medicinal products and medical devices varies depending on whether the purchaser is state-owned or not. Medical institutions controlled by the Chinese government, such as public hospitals, must acquire medicinal products and medical devices through a designated bidding process through a government-run public online platform, while for other medical institutions, participation in the bidding process is only encouraged but not mandatory. For state-owned purchasers, to streamline distribution, a two-invoice system regulates that only up to two VAT invoices can be issued along the distribution chain of pharmaceutical product procurement, with one issued by manufacturers and the other by the first-tier distributor.

In addition, volume-based procurements are carried out from time to time at the national or provincial level for certain medicinal products listed in the national reimbursement list and high-value medical consumables characterized by large consumption and high procurement price. The governments organize the procurement and determine the procurement volume, and the MAHs may participate in bidding.

b) Food Supplements

In principle, any entity that has obtained the regulatory approval for food business operation is qualified to distribute food supplements in the PRC, except that (i) "Specific Whole Nutritional Formula Food" shall be distributed by medical institutions or pharmaceutical retailers only, and no additional regulatory approval for food operation is required; (ii) selling pre-packaged food supplements requires filing with relevant local administration department, and (iii) manufacturers with regulatory approval for food manufacturing may distribute food supplements at its manufacturing facilities or via the Internet.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

a) Medicinal Products & Medical Devices

Pricing. As described above, medicinal products and high-value medical consumables shall be purchased through a government-run public online platform. In certain provinces, regulatory authorities require that the displayed price on their platform be the lowest price among those listed on platforms operated by other provincial regulatory authorities. If such medicinal products are exclusively listed in the national reimbursement list, the price displayed on such platform will be based on the reimbursement standards for medicinal products covered by medical insurance (the "Reimbursement Standards") as determined through negotiations between the government authorities and the MAH; if such medicinal products are non-exclusive and are included in the "Volume-Based Procurement" list, the Reimbursement Standards will be determined during the "Volume-Based Procurement" activities accordingly; and if such medicinal products are non-exclusive and are not included in the "Volume-Based Procurement" list, the Reimbursement Standards will be determined by competitive bidding for inclusion in the National Drug Reimbursement List or otherwise.

Reimbursement. With respect to medicinal products, the central government authority periodically updates the national reimbursement list based on reviews and comments from healthcare professionals, negotiations with MAHs (for exclusive medicinal products), or competitive bidding for inclusion in the National Drug Reimbursement List (for non-exclusive medicinal products). With respect to medical devices, provincial government authorities issue their own reimbursement lists. There is a recently circulated draft guideline governing the reimbursement of medical devices at a national level.

b) Food Supplements

Currently, there are no specific pricing rules or reimbursement rules for food supplements.

14. What legislative framework applies to the advertising for medicinal products,

medical devices, and food supplements in your country?

Medicinal products, medical devices, and food supplements (collectively, "MMF") are subject to both overarching advertising laws and regulations, as well as certain specific laws and regulations related to MMF.

a) General Advertising Laws and Regulations

The fundamental and general laws in the field of advertising include the *Advertising Law*, the *Regulations for the Control of Advertising*, and the *Administrative Measures for Internet Advertising*. These legal provisions establish the basic requirements for commercial advertising activities and form the foundation of the regulatory system for pharmaceutical advertising.

Certain other laws also regulate advertising, including the *Unfair Competition Law*, the *Consumer Protection Law*, the *Trademark Law*, the *Copyright Law*, and the *Patent Law*. These laws or regulations prohibit false, misleading, or malicious advertising, infringements of intellectual property rights, and other unfair competition practices. They also define legal liabilities for false advertising and deceptive promotions that harm consumers' rights and establish guidelines for intellectual property matters in commercial advertising activities.

b) Specific MMF Advertising Laws and Regulations

In addition to the aforementioned, there are laws and regulations specifically applicable to MMF advertising. These include:

- *Measures for the Administration of Medical Advertisements*
- *The Interim Measures for the Examination and Administration of Advertisements for Medicinal Products, Medical Devices, Healthcare Food and Food Formulas for Special Medical Purpose*
- *Drug Administration Law*
- *Regulation on the Supervision and Administration of Medical Devices*
- *Food Safety Law*

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

a) General Laws and Regulations relating to Patents and Trademarks

- *Patent Law*
- *Implementation Regulations for the Patent Law*
- *Guidelines for Patent Examination*
- *Trademark Law*
- *Implementation Rules for the Trademark Law*
- *Guidelines for Trademark Examination*

b) Laws and Regulations Specifically relating to Trademarks for Medical Products, Medical Devices, and Food Supplements

- *Drug Administration Law*
- *Rules for Drug Insert Sheets and Labels*
- *Administrative Measures for the Registration and Filing of Healthcare Food*

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

a) Possible Defense Strategies against Patent Infringement

- Defense based on patent validity: Challenging the validity of the patent right.
- Defense based on abuse of patent right: Asserting that the acquisition of the patent right was in bad faith.
- Defense based on non-infringement: Asserting that the accused technical solution lacks at least one technical feature defined in the allowed claims.
- Defense based on prior art: Asserting that the accused technical solution belongs to the prior art.
- Defense based on legitimate source: Asserting being unaware of the patent infringement and proving the legitimate source of the product, resulting in no liability for compensation.

b) Applicable Legal Proceedings against Patent Infringement

- Litigation for Patent Infringement: After a patent is granted, the patentee or other beneficiaries may initiate litigation against those who practice the patented medical products or devices without the patentee's consent.
- Litigation Utilizing the Drug Patent Linkage System: During the review process for

marketing authorization of new drugs, the applicant for marketing authorization, the relevant patentee, or other beneficiaries may file a lawsuit to seek a determination as to whether the technical solution of the new drugs falls within the scope of existing drug patent.
- Injunctive Relief: A party may seek injunctive relief, i.e., requesting the court to order the relevant parties to take certain actions or prohibit them from taking certain actions (e.g., stopping infringement) before or during litigation.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

There are some regulatory restrictions on the use of trademarks for drugs and certain food products:

a) Restrictions on the Use of Trademarks for Drugs

Common names of drugs (i.e. drug names included in the National Drug Standards) cannot be used as trademarks for drugs. Unregistered trademarks cannot be used in drug insert sheets and labels. Besides, the font and printing of registered trademarks used in drug labels shall comply with relevant regulatory requirements.

b) Restrictions on the Use of Trademarks for Certain Food Products

For formula food for special medical purposes, the form of its trademark shall comply with the Guidelines for the Labeling of Formula Food for Special Medical Purposes. For special whole nutrition formula food: It is prohibited to use any trademark identical to the name of special whole nutrition formula food to publish any advertisement in a disguised manner in any media other than professional medical or pharmaceutical journals, or use such trademark to name any activity for advertisement.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

China imposes a regime of no-fault civil liability for defective products. MAHs, manufacturers, and suppliers may also face criminal liability if their products are defective or unsafe. Specifically:

For medicinal products & medical devices, the MAHs, manufacturers, and medical institutions may face various forms of liabilities, including (i) civil liability in the form of monetary compensation to patients; (ii) administrative liability, such as warnings, fines, detention, revocation of authorization; and (iii) criminal liability, including fixed-term imprisonment, life imprisonment, or even death penalty, along with fines or confiscation of property.

For food supplements, food manufacturers and distributors may face various forms of liability, including civil/monetary compensation, administrative penalties such as fines, cancellation of permits, being ordered to suspend production or business, and criminal liability such as fixed-term or life imprisonment or even death penalty.

For civil liabilities, a party, whether it is the MAH, the manufacturer, or the medical institution (or food supplements manufacturer or distributor in the context of food supplements), may not be exempted from liabilities solely on the ground that other parties are liable but the party held liable have the right of recourse to the responsible party after making the compensation. However, parties may be exempted from liabilities if (i) the product has not been put into circulation; (ii) the product defect causing the damages does not exist when the product is put into circulation, and (iii) the scientific and technological level at the time when the product is put into circulation is not capable of detecting the defect.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

a) Criminal Liability

For medicinal products, manufacturers or distributors may face criminal liabilities for manufacturing or selling drugs, or providing counterfeit drugs or inferior drugs, or hindering drug administration.

For medical devices, criminal responsibility primarily revolves around the manufacturing or distribution of medical devices that fail to meet established standards. A surge in such cases has been observed during the

COVID-19 pandemic, where individuals were consistently discovered engaging in the manufacturing and distribution of medical devices, such as virus protective suits and masks, without the necessary production and business qualifications.

For food and food supplements, individuals may be held criminally liable for manufacturing or distributing toxic or harmful food, or food that does not meet safety standards.

b) Administrative Liability

Administrative liability, including warnings, fines, revocation of manufacturing or operation licenses, and confiscation of illegal gains, may be imposed in cases involving sale of medicinal products without required licenses, sale of counterfeit drugs, failure of medical device manufacturing or sales companies to fulfill recall, reporting, or other obligations, or food and food supplement companies engaging in unauthorized food production or providing false materials when applying for food supplement registration.

c) Civil Liability

For medicinal products and medical devices, the MAHs, manufacturers, and medical institutions may be held liable for civil liabilities, typically in the form of monetary compensation, if the medicinal products or medical devices caused harm to patients. Similarly, in the case of food or food supplements, food manufacturers and distributors may be held liable to customers for harmful food.

d) Anti-Corruption in Medical Sector

Since mid-2023, an anti-corruption campaign has been observed in the medical and pharmaceutical sectors, regulatory authorities and disciplinary inspection committees in at least 20 provinces have addressed anti-corruption concerns publicly, urging a thorough crackdown on corruption in the pharmaceutical sector. Around a hundred listed pharmaceutical companies have publicly responded to anti-corruption inquiries. According to a public announcement by the National Health Commission, the anti-corruption campaign will focus on six aspects, including the corruption issues in the sales and procurement of pharmaceutical products.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Emerging digital health applications, with digital therapeutic products (DTx products) serving as prime examples, are increasingly capturing the regulatory spotlight in China. In the context of Chinese legal regime, regulatory oversight of DTx products varies depending on their product type, methods of efficacy acquisition, and intended use, resulting in classification as either medical devices or non-medical devices. DTx products regulated as medical devices shall follow the medical device regulations, covering aspects such as clinical research and development, product registration, manufacturing, distribution, commercialization, and promotional activities.

China is actively refining regulatory standards for DTx products, as evidenced by initiatives such as the drafting of the Guiding Principles for the Classification of Digital Therapeutic Medical Device Products (Draft) in 2022. Moreover, several provinces in China have successively launched policies to promote the development of DTx. (for further interpretation, please refer to: How Digital Therapeutics (DTx) Products are Regulated in China?)

In addition to DTx products, a more extensive range of digital health applications may involve diverse digital therapeutic products such as comprehensive health and wellness mobile applications and internet hospital platforms. Concerning the extensive scope of digital health applications, within the Chinese regulatory framework, various regulatory aspects are closely intertwined. These include, but are not limited to, internet diagnostic and therapeutic compliance, advertising compliance, personal information and data security protection, and human genetic resource protection.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

China has implemented laws and regulations to protect the supply of medicinal products and medical devices, ensuring their quality, safety, and availability to meet the healthcare needs of the population.

The National Health Commission and National Administration of Traditional Chinese Medicine are responsible for issuing and regularly updating the *National Essential Medicines List*. This list includes essential medicines deemed necessary for basic

healthcare in China and serves as a reference for procurement, pricing, and supply in the public healthcare system.

To ensure the availability and affordability of essential medicinal products, China has implemented centralized procurement mechanisms for certain medicines and medical devices. These mechanisms involve negotiating lower prices and securing the supply of essential items through bulk purchasing arrangements with manufacturers.

China has also established a shortage medicines management system, which includes creating a list of shortage medicines and implementing cooperative monitoring and early warning systems. National and local governments have reserved essential medicines and medical devices for allocation during emergencies, ensuring a continuous supply of critical medical resources.

In the event of public health emergencies such as epidemics or pandemics, the government has the authority to mobilize reserved medicines and medical devices and can issue compulsory licenses for patented drugs or initiate a prioritized review and approval process for urgently needed shortage medicines and new drugs.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

The China Chemical Pharmaceutical Industry Association (CPIA) issued the *Pharmaceutical Industry Compliance Management Standards* in March 2021. These standards impose stringent requirements on pharmaceutical companies, covering areas such as anti-commercial bribery, product promotion, invoice verification, and expense reimbursement.

For the medical device industry, the China Association for Medical Devices Industry (CAMDI) developed the *Medical Device Industry Code of Conduct*. This code addresses various aspects of marketing and sales of medical devices, including transparent pricing, fair competition, and appropriate interactions with healthcare professionals.

The R&D-based Pharmaceutical Association Committee (the “RDPAC”), a prominent industry association representing multinational pharmaceutical corporations, regularly updates the *RDPAC Code of Conduct*. This code provides guidelines for ethical behaviours and promotional activities related to medicinal products. It includes requirements for fair competition, use of clinical trial data in a responsible way, and appropriate interactions with healthcare professionals.

In addition to industry-specific codes, pharmaceutical and medical device companies operating in China must adhere to anti-bribery laws such as the *Anti-Unfair Competition Law*, the *Criminal Law*, and the *Foreign Corrupt Practices Act* (FCPA). These laws prohibit any forms of corruption including bribery and kickbacks in business practices.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

a) Starting from the issuance of the *Notice on Correcting Improper Practices in Medical Procurement and Services*, jointly released by 14 central government ministries and commissions on May 8, 2023, China has launched an unprecedented campaign to combat corruption in the medical and pharmaceutical sectors. One significant change this year is the expansion of the inter-ministerial working mechanism, with the number of participating departments increased from 9 to 14. This demonstrates the Chinese government’s strong determination to crackdown on all forms of corruption and improper conduct in the pharmaceutical industry.

b) In December 2023, the State Council of China announced amendments to the *Implementing Rules for the Patent Law*. Effective from January 20, 2024, these amendments notably refine the pharmaceutical patent term extension system, which was first established in the 2020 revision of the *Patent Law*. The revised implementation rules also provide detailed provisions on the conditions for applying for patent term compensation, the calculation of the compensation period, and the scope of protection during the compensation period.

c) On December 29, 2023, the 14th National People’s Congress Standing Committee of China passed the 12th amendment to the *Criminal Law*, which will be effective from March 1, 2024. This amendment aims to, among others, strengthen penalties for bribery, particularly in the life sciences sector. It refines the circumstances under which harsher penalties may be imposed for bribery practices, including instances of bribing multiple individuals, bribery by government officials, bribery in

major projects and job promotions, bribery targeting government officials or judicial staff, and in critical sectors such as food, drugs, and healthcare services.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

a) The digitalization of the healthcare system and the application of artificial intelligence in the life sciences sector have brought issues such as industry compliance, data security, and scientific and technological ethics to the forefront of governmental authorities' concerns. Government authorities are expected to strengthen their oversight of AI-based medical software, online hospitals, remote diagnostics, and foreign investment in AI-related pharmaceutical sectors.

b) Data Security and Personal Information Protection: Given that the pharmaceutical industry handles extensive personal information and public health data, government authorities are enhancing healthcare-related legislation concerning cybersecurity, data security, and personal information protection. The collection, storage, use, and cross-border transfer of patients' personal data, as well as the collection, preservation, utilization, and provision of human genetic resource data, must comply strictly with applicable laws and regulations.

c) Sci-tech Ethics Review: Organizations such as colleges, scientific research institutions, medical and health organizations, and business enterprises engaged in life sciences, medical sciences, artificial intelligence, and other technological activities are likely to fall under the purview of sci-tech ethics review. If the research activities involve sensitive areas of sci-tech ethics, the relevant organizations shall establish a sci-tech review committee to assess ethical risks and conduct reviews of their activities (particularly those activities involving data and algorithms).

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

a) Legislation on medical device has made significant progress.

China is currently working on the pre-legislative study of the *Medical Device Administrative Law*. In September 2023, the legislative program of the 14th National People's Congress Standing Committee has been officially released, where the *Medical Device Administrative Law* has been included for the first time. If such law enters formal legislative stage and is promulgated in the future, it will override the *Regulations for the Supervision and Administration of Medical Devices* to become the highest level of laws in the regulatory regime of medical devices.

b) China continues to promote innovation in drug and medical device industry.

In recent years, the Chinese government is striving to promote innovative drugs and medical devices. A number of supporting policies have been released. The NMPA continues to advance the reform of the review and approval system for drugs and medical devices, which accelerates the market access of high-quality innovative drugs and medical devices. Also, the National Healthcare Security Administration strongly supports the entry of innovative drugs and medical devices into the medical insurance catalog, which helps to open up markets for innovative drug and medical device companies while also improving accessibility for the patients.

c) The market is witnessing a significant increase in license-out transactions.

China's life sciences sector has witnessed a flourishing trend of licensing-out transactions in recent years. The number, deal size and categories of licensed products all have increased significantly. For Chinese domestic biotech and pharmaceutical companies, licensing-out deals have become a popular method to cash out as well as to share risks pertaining to innovative drugs and medical devices.

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