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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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China: Life Sciences

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

Medicinal products (referred as "drug" below)

The regulatory framework for drugs in the People's Republic of China (the "**PRC**", and only for the purpose of this guide, exclusive of the province of Taiwan and the Special Administrative Regions of Hong Kong and Macau) covers the entire life cycle, from R&D, registration, manufacturing, and distribution to use and post-marketing supervision. The Drug Administration Law serves as the core legislation, establishing the fundamental principles of drug management and regulatory requirements for each stage, applicable to all types of drugs. This core legislation is complemented by administrative regulations and a series of departmental rules. For example, the Regulations for the Implementation of the Drug Administration Law provides specific interpretations and supplements to the Drug Administration Law. Departmental rules such as the Provisions for Drug Registration and the Provisions for the Supervision and Administration of Drug Manufacturing further refine regulatory requirements for each stage.

Medical Devices

In PRC, medical devices are categorized into three classes based on their risk levels. The regulatory authority implements different management for three different categories of medical devices at each stage, including market entry, manufacturing, distribution, and use, in accordance with their respective risk levels. The regulatory system for medical devices in PRC is principally governed by the Regulations on the Supervision and Administration of Medical Devices, which covers fundamental aspects such as registration and filing, manufacturing, distribution, use, adverse event handling, and recalls. This is supplemented by departmental rules such as the Provisions for Medical Device Registration and Filing and the Provisions for Supervision and Administration of Medical Device Manufacturing, which provide detailed provisions.

Food and Food Supplements

The regulation of food and food supplements (classified as "**health food**" in PRC) is principally governed by the Food Safety Law, which sets out basic provisions for the supervision of food production, processing, sales, transactions, and recalls. This is supplemented by administrative regulation (i.e. the Regulations for the Implementation of the Food Safety Law) and a series of departmental rules, such as the Measures for the Administration of Health Food Registration and Filing.

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 PRC implements a life-cycle regulation for drugs and medical devices from R&D, registration, manufacturing, distribution, use, and post-marketing evaluation, which shall be regulated by Drug Administration Law, the Regulations for the Implementation of the Drug Administration Law and the Regulations on the Supervision and Administration of Medical Devices. The regulatory process and the rules to be observed at each stage are as follows:

R&D Stage: Clinical trials for drugs and Class III medical devices posing a higher risk to human body, must be pre-approved by the National Medical Products Administration ("**NMPA**") and the ethics committee. Clinical trials must comply with relevant quality standards. The regulations to be followed at this stage include the Good Clinical Practice for Drug Clinical Trials, the Good Laboratory Practice for Non-Clinical Research of Drugs, and the Good Clinical Practice for Medical Device Clinical Trials.

Marketing Registration or Filing: New drugs and Class II and III medical devices shall obtain the registration certificates before market entry. Class I medical devices must be filed before market entry. The regulations to be followed at this stage include the Provisions for Drug Registration, the Provisions for Medical Device Registration and Filing, and the Provisions for In Vitro Diagnostic Reagent Registration and Filing.

Manufacturing: Manufacturing enterprises of drug or

Class II and III medical devices shall obtain corresponding license before manufacturing while the manufacturing enterprises of Class I medical devices need to conduct filing process. The regulations to be followed at this stage include the Provisions for the Supervision and Administration of Drug Manufacturing, the Good Manufacturing Practice for Drug Products, the Provisions for Supervision and Administration of Medical Device Manufacturing, and the Good Manufacturing Practice for Medical Devices.

Distribution and Use: Enterprises engaged in the distribution and sale of drugs or Class II and III medical devices shall obtain the corresponding distribution license. Medical institutions shall establish and improve quality management systems to ensure the safe use of drugs and medical devices. The regulations to be followed at this stage include the Measures for the Supervision and Administration of the Quality of Drug Distribution and Use, the Good Distribution Practice for Drug Products, the Good Distribution Practice for Medical Devices, the Measures for the Supervision and Administration of the Quality of Medical Device Use, and the Measures for the Administration of Clinical Use of Medical Devices.

Post-Marketing Supervision: The post-marketing supervision measures include change control management, tracking of adverse events/reactions, product traceability and recalls, advertising review and etc. The regulations to be followed at this stage include the Measures for the Administration of Post-Marketing Changes of drug (Trial), the Measures for the Administration of Adverse Event Monitoring and Re-Evaluation of Medical Devices, the Good Vigilance Practice for Drug Safety, the Measures for the Administration of Drug Recalls, the Measures for the Administration of Reporting and Monitoring of Adverse Drug Reactions, the Measures for the Administration of Medical Device Recalls, and the Interim Measures for the Administration of Advertising Review of drug, Medical Devices, Health Foods, and Special Medical Purpose Formula Foods.

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.

Food supplements could be classified in to a type of special food (i.e. health food) in PRC, of which the regulatory process shall comply with the Food Safety Law, the Regulations for the Implementation of the Food Safety Law, and the Measures for the Administration of Health Foods. Specifically, the regulatory process at each stage are:

Registration Stage: Health foods using raw materials not listed in the approved directory and the first-time imported health foods are subject to prior approval (in the form of a registration certificate) by the State Administration for Market Regulation (the "**SAMR**"). Other health foods are subject to filing by the local Administration for Market Regulation (the "**AMR**").It is worth noting that prior to the announcement of the Detailed Rules for Technical Evaluation of New Functions and Products of Health Foods (Trial) (the "**New Function Health Food Regulations**") by the SAMR on August 13, 2023, if an enterprise wished to launch a product with a new function not listed in the approved function directory (the "**Function Directory**"), it was required to apply for an adjustment to the Function Directory before the registration of such product. The New Function Health Food Regulations allows enterprises to bring products to market before the new function is officially approved for the Function Directory, subject to pre-market associated approval of the new function and the new product, as well as post-marketing evaluation of the product. The regulations to be followed at this stage include the Measures for the Administration of Health Food Registration and Filing, the Measures for the Administration of Health Food Raw Material Directory and Health Function Directory, the Rules for the Review of Health Food Registration, and the Interim Implementation Rules for the Evaluation of New Functions and Product Technology of Health Foods.

Production Stage: Production Enterprises of health foods shall obtain a Food Production License issued by the provincial AMR and subject to GMP requirements as well as irregular inspections by AMRs. The regulations to be followed at this stage include the Review Rules for Health Food Production Licensing and the Measures for the Administration of Food Production Licensing.

Sales and Distribution: Operators only selling pre-packaged foods (including health foods) shall obtain a business license and file with the county-level AMR. The regulations to be followed at this stage include the Measures for the Administration of Food Business Licensing and Filing.

Advertising and Promotion: The release of health food advertisements requires prior approval from the provincial AMR. The labels, instructions, and advertising content of health foods shall specify that health food is not a drug and cannot replace drug to treat diseases. The

regulations to be followed at this stage include the Interim Measures for the Administration of Advertising Review of drugs, Medical Devices, Health Foods, and Special Medical Purpose Formula Foods.

Post-Marketing Supervision: Enterprises shall promptly report adverse reactions post-market, taking measures such as halting production and recalls. The regulations to be followed at this stage include the Measures for the Administration of Food Recalls.

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?

The post-marketing obligations of marketing authorization holders for drugs and registrants of medical devices (referred to as "**holders**") are similar, but the obligations of drug holders are more detailed and stringent, mainly manifested in the following aspects:

Post-marketing Studies: Holders shall conduct continuous research on their marketed products to assess the safety, efficacy, and quality controllability of the products and regularly carry out post-marketing re-evaluations.

Change Management: Holders shall promptly report, register, or apply for approval from the regulatory authorities for any post-marketing changes (e.g., changes in manufacturing processes, quality standards, formula composition, manufacturing sites, packaging labels, etc.).

Adverse Event Monitoring and Reporting: Holders shall establish a comprehensive vigilance system to actively collect and track information on adverse reactions/events, report them to the regulatory authorities in a timely manner, and take risk control measures.

Product Traceability and Recall: Holders are required to establish and implement a product traceability system to ensure that products can be traced. In the event of problematic products, they shall immediately cease sales, recall the products, and publicly disclose recall information.

Maintenance of Quality Management Systems: Holders of drugs must dynamically implement GMP standards and establish a comprehensive quality control system covering the entire manufacturing and distribution chain. Holders of medical devices must ensure the effective operation of their QMS and submit annual self-inspection reports on quality management.

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?

The regulatory authorities for drugs and medical devices in PRC are primarily NMPA and local medical products administrations (the "**MPA**"). The NMPA is responsible for drafting relevant laws and regulations, formulating quality management standards for the research, manufacturing, distribution, and use of drugs and medical devices, and supervises their implementation. It is also responsible for the registration approval of drugs and medical devices, as well as post-marketing supervision and administration (e.g., organizing adverse event monitoring and re-evaluation). Local MPAs are responsible for the filing and registration of medical devices other than Class III devices, the issuance of drug manufacturing licenses, and routine supervision and law enforcement (e.g., issuance of drug distribution licenses, inspection of retail drug enterprises).

The regulatory authorities for food and food supplements are primarily SAMR and local AMRs. SAMR is responsible for the overall supervision of food production, distribution, and catering services, formulating and supervising the implementation of food safety standards, and organizing the registration, filing, and supervision of special foods. AMR is responsible for the routine supervision and law enforcement of food and food supplements (e.g., issuance of food distribution licenses). The National Health Commission ("**NHC**") focuses on food safety risk assessment and the formulation of safety standards.

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.

If the applicants for the registration of drugs, medical devices, or food supplements disagree with an administrative decision made by the regulatory authority (such as a refusal to register), they should first submit an objection request to the original decision-making

authority, which will reassess and make a new decision. If the applicants still disagree on the review decision by the original decision-making authority, they may apply for administrative reconsideration to the higher-level administrative authority or initiate administrative litigation in court. Specifically:

Objection Request: The applicant could submit an objection request to the original decision-making authority (such as the Center for Drug Evaluation ("**CDE**"), the Center for Medical Device Evaluation ("**CMDE**") under NMPA, or the Center for Food Evaluation ("**CFE**") under SAMR) within the prescribed time limit (i.e. 15 working days for drugs/medical devices and 20 working days for food supplements upon receiving the original decision), stating the reasons and basis for the objection.

Assessment and Feedback: Upon receiving the objection, the review authority will conduct a comprehensive assessment of the content and provide feedback to the applicant within the prescribed time limit.

Administrative Reconsideration or Litigation: If the applicant still disagrees with the review decision by the original decision-making authority, they may apply for administrative reconsideration to the higher administrative authorities (e.g., the NMPA or the SAMR) or initiate administrative litigation in court.

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 PRC, the regulatory framework for drug clinical trials is composed of the Drug Administration Law and its implementation regulations, the Provisions for Drug Registration, the Good Clinical Practice for Drug Trials, and a series of technical guidance principles related to drug clinical trials issued by the NMPA and its subordinate, CDE.

In PRC, clinical trials must be conducted for drugs, except in special circumstances. The initiation of drug clinical trials requires approval from the NMPA. The acceptance and technical review of drug clinical trial applications are handled by the CDE. The approval process for drug clinical trials follows an "implied consent" mechanism, where the CDE must decide whether to approve the clinical trial within 60 working days from acceptance of the application; if the CDE does not provide notifications within 60 working days, it is deemed as consent and the sponsor may proceed with the clinical trial.

The regulatory framework for clinical evaluations of medical devices is composed of the Regulations on Supervision and Administration of Medical Devices, the Provisions for Medical Device Registration and Filing, the Good Clinical Practice for Medical Device Trials, and a series of technical guidance principles related to clinical evaluations of medical devices issued by the NMPA and its subordinate, CMDE.

In PRC, medical devices must conduct clinical evaluation, which can be conducted through clinical trials or by analyzing and evaluating clinical literature and data from similar medical devices. If the NMPA believes that existing clinical literature and data are insufficient to confirm the safety and efficacy of a medical device, then clinical trials shall be conducted. The NMPA has established a "Catalog of Medical Devices Exempt from Clinical Evaluation" and devices listed in this catalog are exempted from clinical evaluation. For medical devices that require clinical trials, if such device is classified as Class III medical device and poses a high risk to human body, clinical trials of such device shall be approved by the NMPA. The approval process for medical device clinical trials also follows an "implied consent" mechanism, where the CMDE must decide within 60 working days from acceptance of the application, if the CDE does not provide notifications within 60 working days, it is deemed as consent. Other medical devices conducting clinical trials only need to be filed with the MPA at the provincial level.

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

According to the Announcement of the NMPA on the Drug Clinical Trial Information Platform and the Rules on the Registration and Information Disclosure Management of Drug Clinical Trials (Trial), the NMPA has established a platform for the registration and information disclosure of drug clinical trials (http://www.chinadrugtrials.org.cn/index.html). However, the NMPA has not established a similar platform for clinical trials of medical devices.

Provisions for Drug Registration require sponsors to register the drug clinical trial protocol and other information on the drug clinical trial registration and information disclosure platform before conducting drug clinical trials. The registered information is publicly disclosed on the platform, and the sponsor is responsible

for the authenticity of registration information.

According to the Regulations on the Registration and Information Disclosure Management of Drug Clinical Trials (Trial), applicants should register on the platform before conducting clinical trials in any of the following situations: (1) Clinical trials that have obtained approval from the NMPA and are conducted within PRC; (2) Clinical trials that have completed the filing of chemical drug bioequivalence tests and have obtained a filing number; (3) Phase IV clinical trials and post-marketing studies conducted in accordance with the requirements of the drug registration certificate or notifications issued by the NMPA; (4) Other situations that require registration in accordance with regulatory requirements.

There is another registration institution in the PRC, the Chinese Clinical Trial Registry (ChiCTR, https://www.chictr.org.cn/about.html), which is a primary registration agency for the World Health Organization's International Clinical Trials Registry Platform (ICTRP). It is a non-profit academic institution, and registration with ChiCTR is voluntary, primarily aiming at publishing academic research in medical journals.

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

Provisions regarding the use of clinical trial data in PRC are scattered across multiple laws, administrative regulations and rules.

According to the Good Clinical Practice for Drug Clinical Trials, all clinical trials must protect the privacy of subjects and the confidentiality of their information. A unique identification code should be assigned to each participant to identify them, and researchers should use this code instead of the subject's name when reporting adverse events and other trial-related data to protect their privacy.

Under the Personal Information Protection Law, medical health information is classified as sensitive personal information. Processing such information requires obtaining separate consent from individuals and informing them of the necessity of processing sensitive personal information as well as its impact on their rights. When providing personal information to other processors (such as CROs), individuals must be informed of the recipient and give separate consent. The recipient must process personal information within the scope of the stated purposes, methods, and types of personal information.

According to the Regulations on the Management of Human Genetic Resources and its Implementation Rules, if a clinical trial involves human genetic resources, any biotechnological research and development activities or clinical trials utilizing human genetic resources of PRC must comply with relevant laws, administrative regulations, and national provisions regarding biotechnological research and clinical applications. Foreign organizations and institutions that need to utilize human genetic resources for scientific research activities must collaborate with PRC research institutions, universities, medical institutions, or enterprises.

To obtain market approval for relevant drugs and medical devices in PRC, international collaborative clinical trials utilizing PRC's human genetic resources conducted in clinical medical and health institutions do not require approval if such trials do not involve the export of human genetic resource materials. However, they must meet one of the following conditions and file the types, quantities, and intended uses of the human genetic resources with relevant authorities before conducting the clinical trial:

1. The collection, testing, analysis, and disposal of any remaining human genetic resource materials involved are conducted within the clinical medical and health institutions;
2. The human genetic resources involved are collected within the clinical medical and health institutions and tested, analyzed, and disposed of by domestic entities designated in the clinical trial protocol for the relevant drugs and medical devices;

For exploratory research portions of clinical trials related to obtaining market approval for relevant drugs and medical devices, an administrative license for international scientific research cooperation involving human genetic resources must be applied for.

If clinical trial data needs to be transmitted across borders, the enterprise should consider applying for a data security assessment and establishing standard contracts for the outbound transfer of personal information, based on its specific circumstances and those of the clinical trial data, in accordance with the Personal Information Protection Law, Measures for Security Assessment of Data Outbound, and other relevant regulations.

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)?

According to the NMPA's announcements on the implementation of electronic submissions for medical device registrations and drug registration applications, the NMPA has developed corresponding electronic submission systems. Currently, applications for clinical trials of drugs and clinical trials for Class III medical devices that pose a higher risk to human body can be submitted electronically. Moreover, as mentioned above, drug clinical trial registrations can also be completed electronically.

In addition, on July 27, 2023, the CDE released the Technical Guidance Principles for Patient-Centered Drug Clinical Trial Design (Trial), Technical Guidance Principles for Patient-Centered Drug Clinical Trial Implementation (Trial), and Technical Guidance Principles for Patient-Centered Drug Benefit-Risk Assessment (Trial). These guiding principles provide the legal foundation for decentralized clinical trials in PRC. On May 30, 2024, the CDE further issued the Technical Guidance Principles for Applying Decentralized Clinical Trials in Rare Disease Drug Development, offering more specific guidance for clinical research on drugs for rare diseases.

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.

Drugs:

According to the Drug Administration Law and other relevant regulations, the PRC has implemented a drug marketing authorization holder system. The MAHs can either manufacture drugs independently or entrust a drug manufacturing enterprise to manufacture drugs. If MAHs manufacture drugs themselves, they must obtain a drug manufacturing license. If MAHs entrusting others for manufacturing, they must delegate to a qualified drug manufacturing enterprise. MAHs and the entrusted manufacturing enterprise must sign an entrustment agreement and a quality agreement, and strictly fulfill the obligations stipulated in the agreements. Blood products, narcotic drugs, psychotropic drugs, toxic medical drugs, and controlled chemical substances must not be entrusted for manufacturing.

Engaging in drug manufacturing must comply with the conditions specified in the Provisions for the Supervision and Administration of Drug Manufacturing. The drug manufacturing license for MAHs who produce drugs independently is classified as Class A. For MAHs who entrust manufacturing, it is classified as Class B, while the entrusted manufacturing enterprise holds Class C drug manufacturing licenses, and the manufacturing enterprise for APIs holds Class D drug manufacturing licenses.

Medical Devices:

Similar to drugs, according to the relevant provisions of the Regulations on the Supervision and Administration of Medical Devices, medical device registrants and filers may manufacture medical devices themselves or entrust the manufacturing to enterprises that meet the requirements of relevant regulations and possess the necessary conditions. Medical device registrants and filers must sign a entrustment agreement with the entrusted production enterprise, clarifying rights, obligations, and responsibilities of both parties. The entrusted manufacturing enterprise must organize production in accordance with laws and regulations, the quality management standards for medical device production, mandatory standards, product technical requirements, and the entrustment agreement, taking responsibility for the production activities and accepting supervision from the MAHs. High-risk implantable medical devices must not be entrusted for manufacturing, and the list of such medical devices (the “List of Medical Devices Prohibited from Entrustment Manufacturing”) shall be formulated by the NMPA.

Those engaged in medical device production activities must meet the specified conditions in the Regulations on the Supervision and Administration of Medical Devices. Those engaged in the manufacturing of Class I medical devices must file with the MPAs at the municipal level, completing the filing upon submission of relevant materials; those engaged in the manufacturing of Class II and Class III medical devices must apply for a production license from MPAs at provincial level and submit relevant materials along with the registration certificate for the medical devices being manufactured.

Food and Food Supplements:

According to the Implementation Regulations of the Food Safety Law, food producers and operators who entrust the production of food must delegate to producers who have obtained food production licenses, and they are responsible for supervising the manufacturing activities and ensuring the safety of the food. The entrusted party must produce in accordance with laws, regulations, food safety standards, and contractual agreements, take responsibility for the production activities, and accept

supervision from the entrusting party.

In January 2024, the State Administration for Market Regulation issued a notice on the Draft Measures for the Supervision and Administration of Food Entrustment Production (for public consultation), which proposes the following regulations:

1. The entrusting party for food production must be a food producer or operator that has obtained a food manufacturing and operation license, or a food operator that has registered only for the sale of pre-packaged foods. The entrusting party for health foods must be the holder of a health food registration certificate and must have obtained the corresponding health food production or operation license (filing).
2. The entrusted party must be a food production enterprise holding a valid food production license, with the scope of the production license covering the types and categories of products being produced under the entrustment and having the corresponding capacity.
3. Both the entrusting party and the entrusted party must report the entrustment situation to the local county-level food safety supervision and management department within 10 days of signing the contract. For long-term contracts with a duration exceeding one year, they must also report the entrustment situation annually.

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.

Drugs:

According to the Drug Administration Law, engaging in drug wholesale activities requires approval from the MPA at the provincial level, and obtaining a drug distribution license. For drug retail activities, approval must be obtained from the MPA at or above the county level, and obtain a drug distribution license.

In PRC, drug companies may sell drugs independently or through drug commercial enterprises. Except in special circumstances, public medical institutions shall procure drugs through centralized online procurement platforms established by provincial governments. Drug manufacturers or their distributors must register the drugs they intend to sell on such platforms and publicly disclose the procurement prices ("online listing"); non-public medical institutions are not required to use such platforms for drug procurement.

Additionally, when selling drugs to public medical institutions, the "two-invoice system" must be followed, meaning that the drug manufacturing enterprise issues one invoice to the distribution enterprise, and the distribution enterprise issues another invoice to the medical institution.

Medical Devices:

According to the Regulations on the Supervision and Administration of Medical Devices and other relevant rules, entities engaged in the business of medical devices must have business premises and storage conditions that are appropriate to their scale and scope of operations, as well as a quality management system and quality management personnel or institutions that are suitable for the medical devices they handle.

No license or filing is required for the distribution of Class I medical devices; for Class II medical devices, the distributing enterprise must file with the local MPA; for Class III medical devices, the distributing enterprise must apply for a distribution license from the local MPA. Medical device registrants and filers can distribute medical devices they have registered or filed without a distribution license or filing, but they must have the corresponding operational conditions.

Similar to drugs, medical device companies can sell independently or through medical device distributors/agents. Generally, public hospitals shall procure medical equipment through public bidding or negotiation. In addition, except in special circumstances, public medical institutions shall purchase high-value medical consumables through centralized online procurement platforms established by provincial governments. Medical device manufacturers or their distributors must register the medical consumables they intend to sell on such platforms and publicly disclose the procurement prices ("online listing"); other non-public medical institutions are not required to use such platforms for procuring medical consumables.

Furthermore, in the process of selling high-value medical consumables to public medical institutions, the "two-invoice system" must also be followed, meaning that the consumable manufacturing enterprise issues one invoice to the distribution enterprise, and the distribution enterprise issues another invoice to the medical institution.

Food Supplements:

According to the Food Safety Law and other regulations,

businesses that only sell pre-packaged health foods do not need to obtain a food operation license. However they must file with the local AMR at or above the county level; food operators who have already obtained a food operation license do not need to file again when adding pre-packaged health food sales; food producers who have obtained a food production license do not need to file again when selling their produced pre-packaged foods at their production and processing sites or through the internet.

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

According to the Notice on the Issuance of the Opinions on Promoting Drug Price Reform jointly issued by the National Development and Reform Commission and other ministries, currently, with the exception of narcotic drugs and Class I psychotropic drugs, the vast majority of drugs can be priced independently by enterprises based on market conditions.

The PRC government will regularly organize centralized procurement for certain drugs (mainly generic drugs that have passed quality and efficacy consistency evaluations) at both national and provincial levels. The enormous demand generated by these public medical institutions serves as leverage in negotiations to lower drug procurement prices. Companies participating in centralized drug procurement must bid competitively and offer substantial discounts. Additionally, since 2019, the National Healthcare Security Administration has organized annual negotiation programmes to select drugs and drugs included in the "National Medical Insurance Drug List" as a result of negotiations will be reimbursed by the national medical insurance fund in accordance with established payment standards.

Similar to drugs, there are currently no pricing rules for medical devices, allowing companies to set prices based on market conditions. Furthermore, the government regularly organizes centralized procurement for high-value medical consumables.

Currently, the PRC government has not established specific pricing rules for food supplements and the prices can be determined independently by enterprises based on market conditions.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The regulations applicable to the advertising of drugs and medical devices and food supplements in PRC can be categorized into two types. The first type consists of general provisions for advertising, which are not only applicable to the advertising of drugs, medical devices and food supplements but also to the advertising of other products. The second type comprises special provisions specifically targeting the advertising of drugs, medical devices and food supplements.

General provisions include but not limited to the Advertising Law, the Regulations for the Control of Advertising, the Administrative Measures for Internet Advertising, the Administrative Measures for the Broadcast of Radio and Television Advertising; Special provisions include the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes, the Drug Administration Law, the Regulation on the Supervision and Administration of Medical Devices, the Food Safety Law.

In addition to the aforementioned, laws and regulations from other fields also provide certain regulations for advertisements. These include, but are not limited to, the Anti-Unfair Competition Law, which prohibits misleading or false advertising, and the Criminal Law, which stipulates false advertising as a criminal offense.

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

In the field of patents, drugs, medical devices, and food supplements in PRC are governed by general patent laws and regulations, including but not limited to the Patent Law, the Implementing Regulations for the Patent Law, and the Guidelines for Patent Review. In addition, there are specific requirements applicable to drugs and food supplements, such as the Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial Implementation), the Administrative Ruling Measures on the Early Resolution Mechanism for Drug Patent Disputes.

In the field of trademarks, drugs, medical devices, and food supplements in PRC are governed by general trademark laws and regulations, including but not limited to the Trademark Law, Implementation Regulations for the Trademark Law, the Trademark Review and Adjudication Rules, and the Guidelines for Trademark

Review and Adjudication. Additionally, there are specific requirements applicable to drugs and food supplements, such as the Drug Administration Law, the Rules for Drug Insert Sheets and Labels, and the 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.

In the event of patent infringement, the patentee or other beneficiaries may negotiate with the infringer to resolve the dispute, and they may also resolve the issue of patent infringement through administrative processing or litigation.

Defensive strategies against patent infringement claims include: non-infringement defense, patent invalidity defense, prior art defense, prior use defense, legitimate source defense, patent exhaustion defense, and patent misuse defense.

The legal procedures for resolving patent disputes are as follows:

(1) Judicial route: Pursuant to the provisions of the Patent Law, a drug market authorization applicant and relevant patentee or other beneficiaries may file a lawsuit against the infringer to the People's Court. First-instance civil cases involving invention patents or utility model patent infringements are under the jurisdiction of intellectual property courts, intermediate people's courts in the locations of provincial governments, or intermediate courts designated by the Supreme People's Court. First-instance civil cases involving design patent infringements fall under the jurisdiction of intellectual property courts and intermediate people's courts.

(2) Administrative route: According to the Patent Law, if a party implements a patent without the permission of the patentee, the patentee or other beneficiaries may request the relevant patent administration to handle the case. If patent administration confirms the infringement, it may order the infringer to stop the infringement immediately. Additionally, drug market authorization applicants and relevant patentee or other beneficiaries may request administrative adjudication from the China National Intellectual Property Administration for patent disputes related to the drug under the registration application.

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

In PRC, drugs, medical devices, and food supplements shall first comply with the general restrictions on trademark usage set forth in the Trademark Law. In addition, PRC imposes the following specific restrictions for drugs as well as certain food and food supplements:

1. Drugs

1. The generic name (the name included in the national drug standards) of a drug cannot be used as a trademark.
2. The trademark used for a drug must be registered (obtained a trademark registration certificate).
3. When a registered trademark is used on a drug label, it must be printed in the corner of the label, and the font size of any text must not exceed one-quarter of the font size used for the generic name.

2. Food and Food Supplements

1. For special medical purpose formula foods, the use of registered trademarks on product labels must comply with size, font, color, and area requirements as outlined in the Guidelines for Labeling Special Medical Purpose Formula Foods.
2. A trademark that is identical to the name of a specific whole nutrition formula food cannot be used for advertising purposes in any media other than professional medical and pharmaceutical journals, nor can it be used to sponsor activities for advertising purposes.

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

In PRC, the product liability of drugs, medical devices, and food supplements in the civil and administrative fields is governed by laws and regulations including: The Product Quality Law, the Civil Code, the Protection of Rights and the Interests of Consumers Law, the Food Safety Law, the Drug Administration Law, and the Regulations on the Supervision and Administration of Medical Devices. Additionally, the Criminal Law provides constituent elements of crimes and penalties for product liability. Specifically:

1. Civil Liability

If a product defect causes personal injury or damage to

property, the injured party may claim compensation from the product's manufacturer or distributor (for drugs, claims can be made against the MAH, manufacturers, distributors, medical institutions). After compensating the injured party, the party may pursue recourse from the actual responsible party. In addition to compensating losses of the injured party, the manufacturer, distributor, and others involved may also be required to pay punitive damages.

Furthermore, product liability in PRC implements on a strict liability basis. Regardless of whether the manufacturer of the defective product was at fault, it shall be liable unless one of the following defenses applies: (1) The product was not released into the market, or it was released without the manufacturer's intent or will; (2) The product did not have the defect that caused the harm when it was released, and the defect only emerged after it entered the market; (3) The manufacturer could not have discovered the defect at the time of release due to the scientific and technological limitations.

2. Administrative Liability

Product liability may result in the following administrative penalties for the relevant entities:

(1) Warning; (2) Order to rectify, suspend manufacturing, distribution, or recall the product; (3) Confiscation of illegally manufactured or distributed products and illegal gains; (4) Fines; (5) Revocation of business licenses, relevant approval licenses, certificates, and permits.

Furthermore, the legal representatives, or other responsible individuals of the related enterprises may face the following administrative penalties: (1) Confiscation of income earned during the period of illegal activity; (2) Fines; (3) A ban of up to ten years or even lifetime prohibition from engaging in drug manufacturing and distributions; (4) Detention.

3. Criminal Liability

If the actions of the MAH, manufacturers, distributors, or medical institutions (for medical devices, food and food supplements, this applies to manufacturers and distributors) reach the criminal thresholds specified in the Criminal Law for counterfeit or inferior drugs, substandard medical devices, foods that do not up to safety standards or are toxic or harmful, they may face criminal penalties. These penalties may include: fines, confiscation of property, criminal detention, fixed-term imprisonment, life imprisonment, or even the death penalty.

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.

1. Civil Liability

As mentioned in question 18, when the product leads to infringement, the manufacturers, distributors, and other responsible parties may be required to assume the relevant civil liability, including: (1) stopping the infringing actions and eliminate the risk; (2) compensating for losses caused by product defects; (3) potentially being required to pay punitive damages.

In addition to product liability, intellectual property infringements and contractual disputes may also give rise to corresponding civil liabilities.

2. Administrative Liability

In PRC, authorities may impose administrative penalties on the relevant entities for the following behaviors: manufacturing or distributing products without approval, failing to meet product quality standards, failing to fulfill recall obligations, engaging in false advertising, abusing a dominant market position or engaging in monopolistic practices, or otherwise violating relevant management regulations.

Depending on the specific circumstances and the severity of the impact, the related enterprises may face the following administrative penalties: (1) Warning; (2) Order to rectify; (3) Order to suspend manufacturing or distribution; (4) Recall of products; (5) Confiscation of illegally manufactured or distributed products; (6) Fines; (7) Confiscation of illegal gains; (8) Revocation of business licenses, relevant approval license, certificates, and permits; (9) Industry bans.

The legal representatives, and other responsible individuals of the relevant enterprises may face the following administrative penalties: (1) Confiscation of income earned during the period of illegal activity; (2) Fines; (3) Occupational bans; (4) Detention.

3. Criminal Liability

The following actions in the drug, medical device, food, and food supplement fields may result in criminal liabilities for the parties involved:

- Drugs: Manufacturing or importation of drugs without

the necessary drug approval licenses, manufacturing of counterfeit or inferior drugs, or hindering drug administration.
- Medical Devices: Manufacturing or distribution of unregistered Class II or Class III medical devices, or Manufacturing, distribution or use of medical devices that do not meet mandatory standards or registered or filed manufacturing technical requirements.
- Food/Food Supplements: Manufacturing or distribution of food/ food supplements that are not up to food safety standards.

Such actions may result in the following legal criminal liabilities: (1) Criminal detention; (2) Fixed-term imprisonment; (3) Life imprisonment; (4) Fines; (5) Confiscation of property; (6) death penalty.

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.

The provision of application information services within the territory of PRC, as well as the engagement in application distribution services such as internet application stores, shall comply with the Regulations on the Management of Information Services of Mobile Internet Applications ("Application Regulations"). Application information services include activities involving creation, copying, publishing, and dissemination of text, images, voice, video, and other information through applications. Digital health applications providing users with health and medical service information through applications, fall within this scope and are required to comply with the regulatory requirements set forth in the Application Regulations regarding the primary responsibility for information content, real-name authentication, classification management, industry self-discipline, social supervision, and administrative management.

For digital health applications, PRC has established a refined regulatory framework tailored to different natures, functions, and types of digital health application software.

Firstly, if digital health application software has one or more medical purposes, such software falls within the category of mobile medical devices and shall comply with relevant PRC regulations on medical devices. In addition to the comprehensive laws and regulations for medical device supervision, digital health application software classified as mobile medical devices shall also adhere to specific software-related medical device regulations such as the Technical Review Guidelines for the Registration of Mobile Medical Devices and the Appendix on Standalone Software of the Good Manufacturing Practice for Medical Device Manufacturing. In addition, depending on the functions of the digital health application software, it shall also comply with different regulatory requirements. For example, digital health application software involving internet medical services shall comply with regulations such as the Interim Measures for the Administration of Internet Hospitals, and digital health application software involving pharmaceutical operations and related functions shall comply with regulations such as the Drug Administration Law and the Interim Provisions on the Approval of Internet Drug Transaction Services.

It shall also be noted that the use of digital health applications often involves the protection of users' data and privacy. Medical and health data has unique characteristics and may involve patients' personal information, medical records, health insurance information, human genetic resources, scientific data, and other sensitive information. Currently, PRC has implemented the Personal Information Protection Law and the Data Security Law, which provide a clear legal framework and enforcement standards for the handling and use of personal medical data, with a particular emphasis on the protection of sensitive personal information, categorizing medical and health information as a specially protected category. In addition, when handling specific types of data, digital health applications shall also comply with relevant specialized regulations.

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.

PRC has established a comprehensive system for the supply and security of drugs and medical devices, covering institutional management, emergency supply.

For drugs, PRC implements a shortage drug list management system and establishes a drug supply and demand monitoring system. It clarifies the obligations of drug marketing authorization holders to report shortages and ensure manufacturing and supply, as well as the state's priority review and approval of clinically urgent shortage drugs. For the supply of essential medicines, the PRC government dynamically adjusts the essential drug list, and ensures supply through market matching to determine reasonable procurement prices, centralized production, unified distribution, and inclusion in reserves.

To ensure the supply of shortage drugs, PRC relevant authorities have issued a series of laws and regulations, such as the Opinions on Ensuring the Supply and Guarantee of Essential Drugs for Infectious Disease Treatment and Emergency Medical Care and the Implementation Opinions on Reforming and Improving the Supply Security Mechanism for Shortage Drugs. Currently, the National Health Commission of PRC, in conjunction with members of the national linkage mechanism, formulates and dynamically adjusts the national shortage drug list and the key monitoring list of clinically essential and easily shortage drugs. Shortage drugs are addressed through measures such as implementing centralized production, coordinating emergency production and imports, strengthening supply and demand docking, negotiating adjustments, improving the reserve of shortage drugs, and perfecting policies for rare disease medications. In addition, PRC issued the Temporary Import Work Plan for Clinically Urgent Drugs in 2022, clarifying the temporary import policy for a small amount of clinically urgent drugs that have been marketed abroad but are not registered, produced, or cannot be restored to production in the short term within the country.

For medical devices, PRC has established emergency approval procedures, priority review procedures, and conditional approval to ensure the supply of the medical devices. Under the emergency approval procedure, during public health emergencies, the NMPA implements emergency approval for related medical devices to be quickly marketed according to the principles of early intervention and rapid approval. Through the priority review procedure, medical devices used for specific types of diseases, elderly and children's special diseases, or included in relevant national science and technology plans can be accelerated to some extent. Conditional approval for medical devices refers to the system of approving the marketing of medical device products that are used to treat serious life-threatening diseases without effective treatment methods, after fully considering the balance of pre-market and post-market research data and comprehensively evaluating the risks and benefits of the medical devices, and identifying that the medical device is indeed effective and can play a clinical value. The currently inactive Draft Medical Device Administration Law (Draft for Comments) also proposes that the state implements a medical device reserve system. In the event of major disasters, epidemics, or other emergencies, in accordance with the provisions of the Emergency Response Law, the State Council's industrial and information technology department, in conjunction with relevant departments, can urgently mobilize medical devices.

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 marketing of medicinal products and medical devices in PRC is governed by a comprehensive framework of laws, regulations, and industry codes of conduct.

In the current trend of increasingly strict anti-corruption in PRC's pharmaceutical industry, the marketing of drugs and medical devices domestically needs to pay attention to the risks that constitute commercial bribery. Bribery in PRC may be subject to criminal liability. The Anti-Unfair Competition Law and the Drug Administration Law have made principled provisions on commercial bribery that the provision of property or other improper benefits to persons such as heads of medical institutions, drug procurement personnel, physicians, and pharmacists. In May 2024, the National Health Commission and 14 other ministries and commissions issued the Key Points of Work for Correcting Unhealthy Practices in the Field of Pharmaceutical Procurement and Sales and Medical Services in 2024, which particularly emphasized the focus on issues such as accepting kickbacks under the guise of academic lectures, external testing, external prescription dispensing, and online prescription writing, and the issues of demanding and illegally accepting property using their positions. Therefore, if some drug or medical device manufacturers, under the guise of academic lectures and conferences, actually engage in the transfer of related finances or other improper benefits, they are likely to constitute commercial bribery and face criminal penalties.

In addition, the Pharmaceutical Industry Compliance Management Standards issued by the PRC Pharmaceutical Industry and Chemicals Corporation came into effect on February 26, 2021, aiming to help pharmaceutical companies identify loopholes in industry and legal supervision, streamline regulatory and reporting systems, and formulate and implement effective preventive measures. The Pharmaceutical Industry Compliance Management Standards specifically stipulate anti-commercial bribery and product promotion standards for participants in the pharmaceutical industry, setting corresponding marketing and promotion requirements for drug marketing authorization holders and medical device marketing authorization holders, CROs, CMO/CDMOs, CSOs, and commercial distribution enterprises.

In addition, the RDPAC Code of Practice (2019 Revision) ("RDPAC Practices") of the R&D-based Pharmaceutical Association Committee of the PRC Association of Enterprises with Foreign Investment ("RDPAC") stipulates industry guidelines for medical interactions between companies and healthcare professionals, healthcare organizations, patient organizations, and patients, as well as the promotion of pharmaceuticals. The guidelines apply to RDPAC member companies, but RDPAC encourages non-member companies and other organizations that need to promote pharmaceuticals or services to healthcare professionals or need to engage in interactive activities with healthcare professionals, healthcare organizations, patient organizations, and patients to adhere to ethical behavioral standards similar to those stipulated in the RDPAC Practices for pharmaceutical promotion and related interactive exchanges. However, it should be noted that the RDPAC Practices have limitations such as not being applicable to the promotion of medical devices and not being applicable to the promotion of over-the-counter drugs to consumers.

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.

1. Medical Device Administration Law (Draft for Comments)

On August 26, 2024, the NMPA released the Medical Device Administration Law (Draft for Comments) (the "Draft Medical Device Administration Law"), and solicited public opinions before September 28, 2024. As of the date of this guide, the Medical Device Administration Law has not been promulgated and implemented. Previously, PRC's regulatory provisions for medical devices mainly included regulations and normative documents such as the Regulations on the Supervision and Administration of Medical Devices. There was no specific law for medical devices, but the release of the Draft Medical Device Administration Law marks the entry of PRC's medical device industry into a new era of regulation, applicable to the research, production, operation, use, and supervision and administration of medical devices in PRC. The Draft Medical Device Administration Law consists of eleven chapters and 190 articles, covering the entire lifecycle of medical devices. According to the Draft Medical Device Administration Law, PRC will provide favorable policy support for the development of the medical device industry, including policies to encourage interdisciplinary research, collaboration between enterprises and academic institutions, the establishment of a medical device industry development fund, encouragement of medical device innovation, and international cooperation.

2. Pilot Work Plan for Expanding Openness in the Field of Wholly Foreign-Owned Hospitals

On November 29, 2024, the National Health Commission, Ministry of Commerce, National Administration of Traditional Chinese Medicine, and National Disease Control Bureau announced the Pilot Work Plan for Expanding Openness in the Field of Wholly Foreign-Owned Hospitals (the "Work Plan"). The Work Plan aims to promote the orderly expansion of openness in PRC's medical field, introduce high-level international medical resources, and enrich the supply of medical services in PRC. According to the Work Plan, PRC has lifted restrictions on the establishment of wholly foreign-owned hospitals in Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen, and the entire Hainan Island (excluding traditional Chinese medicine, and not including the acquisition of public hospitals). The Work Plan stipulates the conditions for the investment entities of wholly foreign-owned hospitals and their establishment and operation conditions. In addition, the Work Plan imposes strict restrictions on the diagnostic and treatment activities of wholly foreign-owned hospitals involving human genetic resources, requiring that wholly foreign-owned hospitals not establish hematological hospitals, not register departments of hematology, and not carry out high-ethical-risk diagnostic and treatment activities such as organ transplantation technology, assisted reproductive technology, prenatal screening, and prenatal diagnosis technology.

3. Interim Provisions on the Designation of Domestic Responsible Persons by Overseas Drug Marketing Authorization Holders

On November 13, 2024, the NMPA released the Interim Provisions on the Designation of Domestic Responsible Persons by Overseas Drug Marketing Authorization Holders (the "Interim Provisions"), aiming to strengthen the supervision and management of overseas drug marketing authorizations holders, and to implement the main responsibility for post-marketing quality management, which will be implemented from July 1, 2025. Compared with Interim Provisions on the Administration of Domestic Agents of Overseas Marketing Authorization Holders (Draft for Comments) (the "Draft Interim Provisions") released on July 31, 2020, the content of the Interim Provisions has been significantly modified. Interim Provisions changed the term "domestic agent" used in the previous Draft Interim

Provisions to "domestic responsible person", emphasizing and clarifying the responsibilities of the domestic responsible person. The Interim Provisions define a "domestic responsible person" as a domestic corporate legal person designated by the overseas marketing authorization holders to fulfill the obligations of the drug marketing authorization holders within PRC and to bear joint liability with the drug marketing authorization holders. Article 11 of the Interim Provisions stipulates that the domestic responsible person and the overseas drug marketing authorization holders shall jointly fulfill the following obligations, the establishment of a drug quality system, drug traceability management, drug annual report management, post-marketing change management, pharmacovigilance management, drug complaint and recall management, standard material management, sampling management, daily contact management, and other matters. Although the Interim Provisions stipulate that the obligations are to be "jointly fulfilled" by the domestic responsible person and the overseas holder, it is necessary to provide a "notarized authorized responsibility list" in the domestic responsible person's information submitted to the drug regulatory department, which means that the domestic responsible person needs to clearly define the specific responsibilities they need to bear and establish an effective and adequate quality management system and organizational structure within that scope of responsibility. In addition, for a single drug variety marketed in PRC, the overseas marketing authorization holders shall designate a unique domestic responsible person to fulfill the obligations of the drug marketing authorization holders. The same domestic responsible person can accept designations from different overseas drug marketing authorization holders and different imported drug varieties.

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.

1. Digitalization of the Healthcare System

PRC has established a data security regulatory framework represented by the Cybersecurity Law, Data Security Law, and Personal Information Protection Law. Healthcare data has its unique characteristics, and the PRC government has enacted stricter and more specific regulatory provisions. The Administrative Measures for Cybersecurity in Medical and Health Institutions (the "Administrative Measures") set forth compliance requirements for the network and data security management of medical and health institutions. In terms of data security, with the goal of ensuring the confidentiality, integrity, and availability of data, the Administrative Measures require the adoption of technologies such as data encryption, data backup, and data desensitization to strengthen the security protection throughout the entire lifecycle of data collection, transmission, storage, use, exchange, and destruction. The National Health Medical Big Data Standards, Security, and Service Management Measures (Trial) emphasizes the security management of health medical data, stipulates measures such as data classification, backup, and encryption, and ensures the security of data at every stage. The purpose of this legislation is to provide legal protection for the safe and lawful use of health medical data.

2. Use of Artificial Intelligence in the Life Sciences Sector

PRC government has issued a series of relevant policies, including the Three-Year Action Plan for Internet Plus Artificial Intelligence, Guiding Opinions on Promoting and Regulating the Application and Development of Medical Data, and the Healthy PRC 2030 Planning Outline to encourage and guide the integration of AI with various segments of the medical and health industry. This integration leverages AI technologies represented by computer vision, speech recognition, language processing, and machine learning to achieve cost reduction and efficiency enhancement in drug development, diagnosis, treatment, and health management across multiple scenarios. It empowers various stages before, during, and after hospitalization to meet patient needs. In addition, many regions in PRC have begun to encourage the deep integration of AI technology with clinical medicine, traditional Chinese medicine, and medical management by building innovative platforms and full-domain application scenarios.

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.

1. Further Strengthening Policy Support for Innovative Drugs

In 2024, the PRC government further strengthened the development of innovative drugs across the entire chain. In March 2024, the term "innovative drugs" appeared in the PRC government's work report, and the government's

work tasks for 2024 mentioned "accelerating the development of new quality productive forces", including the development of frontier emerging industries such as innovative drugs. In July 2024, the Implementation Plan for Whole-Chain Support for the Development of Innovative Drugs was approved, proposing to coordinate the use of policies including price management, medical insurance payment, commercial insurance, drug procurement and use, investment and financing optimize the review and approval mechanisms and the assessment mechanisms of medical institutions, and to jointly promote the breakthrough development of innovative drugs. In addition, various provinces in PRC have also introduced policies to support innovative drugs. The first provincial document supporting the whole-chain innovative development of the biopharmaceutical industry was implemented in Shanghai, and Several Measures to Support the Development of Innovative drugs by Guangzhou Medical Insurance was released in May 2024.

2. Anti-Corruption in the Pharmaceutical Field Moves Towards Refined and Comprehensive Governance

In 2024, anti-corruption efforts in PRC's pharmaceutical field further moved towards refined and comprehensive governance, focusing on key links such as pharmaceutical representatives and academic promotion. In November 2024, the NMPA publicly solicited opinions on the Administrative Measures for Pharmaceutical Representatives (Draft for Comments). Once becomes effective, PRC will establish a multi-departmental oversight mechanism for pharmaceutical representatives, which includes healthcare, drug, and medical insurance.

In terms of academic promotion at conferences, academic conferences and professional exchanges that are in compliance with laws are gaining more support. However, if the services provided by the doctor for academic activities lack authenticity, such actions may present a substantial risk of being classified as commercial bribery.

In addition, the NHSA uses the "intelligent supervision" platform, leveraging big data technology for full-chain monitoring of the pharmaceutical circulation process, strictly investigating actions such as inflated pricing and embezzlement of medical insurance funds.

3. Expanded Pilot Initiatives to Open Stem Cell Technology Sector to Foreign Investment

In 2024, PRC expanded pilot initiatives to open its stem cell technology sector to foreign investment, aiming to foster innovation and international collaboration in the biomedical industry. According to the Notice on Expanding Open Pilot Programs in the Medical Field jointly issued by the Ministry of Commerce, the National Health Commission and the NMPA, eligible free trade pilot zones (located in Beijing, Hainan, Shanghai, and Guangdong) will allow foreign-invested enterprises to engage in the development and application of human stem cell, genetic diagnosis and treatment technologies for the purpose of obtaining market authorisation and production. All products approved for registration and production will be permitted for nationwide use. This initiative seeks to attract advanced international technologies and management expertise while mandating strict compliance with PRC laws and regulations, including but not limited to prohibitions on unauthorized use of sensitive data or biological resources.

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