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Research on Full Lifecycle Management of Radiopharmaceuticals

Authors: Zhang Wenxia, Wang Rui, Huang Rui, Xu Dali

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Abstract

Objective Radiopharmaceuticals are the cornerstone of precision medicine. As a special category of pharmaceutical products, their management differs substantially from conventional drugs. China's radiopharmaceutical management started relatively late and still exhibits numerous deficiencies. This study aims to comprehensively explore the current status and trends of radiopharmaceutical development both domestically and internationally, the problems and challenges encountered, and potential solutions and recommendations, thereby providing references for relevant stakeholders and facilitating the establishment of a whole-life-cycle management system for radiopharmaceuticals and sustainable industrial development in China.

Methods This study employs multiple research methods including literature review, case analysis, and questionnaire surveys to investigate whole-life-cycle management of radiopharmaceuticals through retrospective and prospective approaches.

Results Radiopharmaceuticals will become a significant development direction in the future pharmaceutical industry. The development of domestically innovated radiopharmaceuticals in China is progressing rapidly, with continuously expanding market size. However, China has not yet established a comprehensive whole-life-cycle management system for radiopharmaceuticals, and a shortage of qualified technical professionals prevents full satisfaction of patient medical needs.

Conclusion It is recommended to improve the legal and regulatory framework and policy system, increase investment in technology research and development and talent cultivation, actively participate in international cooperation, focus on production supply and distribution as key points, establish and improve the whole-life-cycle management system for radiopharmaceuticals, and enhance the scientific rigor and systematic approach of radiopharmaceutical management in China.

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Full Text

Research on the Full Life Cycle Management of Radioactive Drugs

Authors: Zhang Wenxia, Wang Rui, Huang Rui, Xu Dali
Affiliation: Center for Inspection, Gansu Provincial Drug Administration, Lanzhou, Gansu 730000, China

Abstract:
Radioactive drugs are the cornerstone of precision medicine. As a special category of pharmaceuticals, their management differs significantly from conventional drugs. China's management of radioactive drugs started relatively late and still exhibits numerous deficiencies. This article aims to thoroughly examine the current status and development trends of radioactive drugs both domestically and internationally, analyze the problems and challenges faced, and propose potential solutions and recommendations. This will provide valuable references for the industry and promote the construction of a comprehensive life cycle management system for radioactive drugs in China, ensuring sustainable industrial development. This study employs multiple research methods including literature review, case analysis, and questionnaire surveys, adopting both retrospective and prospective approaches to investigate the full life cycle management of radioactive drugs. The findings indicate that radioactive drugs will become a key development direction in the future pharmaceutical industry. China's original research radioactive drugs are developing rapidly, and the market scale continues to expand. However, China has not yet established a complete full life cycle management system for radioactive drugs, suffers from a shortage of qualified technical personnel, and cannot fully meet patient medical needs. We recommend improving the legal and policy framework, increasing investment in technology research and talent development, actively participating in international cooperation, and focusing on production supply and distribution to establish and improve the full life cycle management system for radioactive drugs, thereby enhancing the scientific and systematic nature of radioactive drug management in China.

Keywords: radioactive drugs; full life cycle; management; challenges; recommendations

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First Author: Zhang Wenxia, female, born in 1985, received bachelor's degree from Shenyang Pharmaceutical University in 2006. Research field: drug review and inspection.

Corresponding Author: Xu Dali, E-mail: 371197851@qq.com

1 Overview of Radioactive Drugs

Radioactive drugs refer to special preparations containing radionuclides used for medical diagnosis and treatment. Those that have obtained national drug approval numbers are called radioactive pharmaceuticals, which are radionuclide preparations or their labeled drugs used for clinical diagnosis or treatment [1].

1.1 Classification of Radioactive Drugs

Based on clinical application, radioactive drugs can be divided into diagnostic and therapeutic categories. Diagnostic radioactive drugs utilize tracer technology to elucidate functional changes, gene expression abnormalities, and biochemical metabolic alterations in pathological tissues at the molecular level [2]. They offer advantages including rapid and accurate results, high sensitivity and resolution, and enable early disease diagnosis for developing more effective prevention or treatment plans. This represents the only technology among all medical diagnostic modalities capable of visualizing metabolic processes in living organisms. Therapeutic radioactive drugs enable selective and targeted treatment of pathological tissues through radionuclides. With technological advancement, particularly the rise of Radionuclide Drug Conjugates (RDC), radioactive drugs have been progressing toward theranostics—where diagnostic molecular imaging can identify lesions, and those same lesions can selectively uptake therapeutic radioactive drugs for internal radiation treatment, enabling personalized diagnosis and therapy. As basic research, clinical studies, and translational applications of novel theranostic radioactive drugs advance, nuclear medicine theranostics will play greater roles in more fields [3].

The classification of radioactive drugs can be further detailed as follows:

Classification	Definition/Principle	Radionuclide/Representative Examples
Diagnostic In Vivo	Utilizes drug radioactivity to obtain images or functional parameters of target organs or lesions	99mTc, 18F, etc.
Diagnostic In Vitro	Uses isotope radioactive characteristics for labeling to improve detection precision	Radioimmunoassay kits, chemiluminescence assays, etc.

Classification	Definition/Principle	Radionuclide/Representative Examples
Therapeutic	Highly selectively accumulates in lesion tissue, producing localized ionizing radiation biological effects to inhibit or destroy pathological tissue	131I, 89Sr, etc.
Cyclotron-produced	Prepared by bombarding stable nuclides with high-speed charged particles from cyclotron	18F, 11C, 15O, 13N
Reactor-produced	Prepared by placing target materials containing relevant nuclei in the reactor core and bombarding with high-flux neutrons to induce nuclear reactions	131I, etc.
Generator-derived	Obtains required daughter nuclide through parent decay	99mTc from 99Mo generator

1.2 Characteristics of Radioactive Drugs

As a special pharmaceutical category, radioactive drugs differ from conventional drugs in production, regulation, transportation, and usage. Their primary feature is the presence of radioactive isotopes that emit radiation at various energy levels, enabling both diagnostic and therapeutic applications. However, due to the special nature of raw materials, their R&D, production, distribution, and use are strictly regulated. Because of radioactive isotopes, these drugs exhibit distinctive characteristics including radioactivity, specific physical half-lives and expiration dates, smaller quantities (with special measurement units), radiation self-decomposition, and instability. In practical application, both efficacy evaluation—selecting appropriate doses to achieve diagnostic/therapeutic goals without causing significant radiation damage—and hazard evaluation must be considered. The latter addresses potential radiation injury to R&D personnel, production staff, patients, and medical workers, as well as environmental

radioactive contamination from improper handling during R&D, production, distribution, preparation, or use [5].

The history of radioactive drugs began in 1896 when Becquerel discovered "mysterious rays" in uranium salts following Roentgen's research. In 1898, Marie Curie first extracted the radioactive element radium, launching human exploration of radioactive drugs. The first study on intravenous radium injection for treating various diseases was published in 1913. In 1946, John H. Lawrence's team achieved the first successful injection of radioactive material into humans for tumor treatment, marking a milestone in radioactive drug therapy. In 1950, Abbott launched the first commercial radioactive drug, 131I Human Serum Albumin (RISA), symbolizing the entry of radioactive drugs into the medical market. In 1970, the U.S. Food and Drug Administration (FDA) gradually revoked exemptions for radioactive drugs and began regulating them as pharmaceuticals, establishing proper oversight. In the United States, radioactive drug research institutions are regulated by the FDA and must follow one of two mechanisms [6]: approval by a Radioactive Drug Research Committee or filing through an exploratory Investigational New Drug (eIND)/Investigational New Drug (IND) application before conducting related research and clinical trials. Although the U.S. lacks exclusive radioactive drug legislation, current major drug regulations consider special documentation requirements for radioactive drug registration and have established multiple technical guidelines [7], including a dedicated review department for radioactive drug approval. The FDA also requires all PET drug production centers to comply with cGMP standards [8], reflecting stringent regulation. Within the EU, diverse legal influences from member states have created varied regulatory structures, with significant differences in radioactive drug management and GMP implementation. For example, France and Hungary only permit radioactive drug use after marketing approval or clinical trial initiation. Austria, the Netherlands, Belgium, and Sweden allow use of specific radioactive drugs prepared under "pharmacy practice" without marketing approval, though these pathways cannot be used for first-in-human trials of new drugs. Germany's Drug Law, Part 2b, Chapter XIII, regulates the use of novel radioactive drugs, permitting physicians to use drugs prepared under their supervision for individual patients [9].

The current U.S. Pharmacopeia and European Pharmacopeia include quality standards for 69 and 70 radioactive drugs, respectively, covering 22 and 19 nuclide types [10]. As of October 2023, 64 novel radioactive drugs have been approved globally, including 50 for diagnosis only, 13 for therapy only, and 1 for both diagnosis and therapy. In 2013, Bayer's radium [223Ra] chloride received FDA approval as the world's first alpha-particle targeted therapeutic drug; prior radioactive drugs mostly lacked targeting capability. In recent years, major multinational pharmaceutical companies have entered the radioactive drug field through acquisitions. In 2017, Novartis acquired Advanced Accelerator Applications for $3.9 billion, and in 2018 acquired Endocyte for $2.1 billion, obtaining two blockbuster therapeutic radioactive drugs: lutetium [177Lu]-oxodotreotide (Lutathera) and lutetium [177Lu]-vipivotide tetraxetan (Pluvicto). In 2023, Eli

Lilly acquired Point Biopharma for $1.4 billion, gaining two Phase III therapeutic radioactive drugs, PNT2002 and PNT2003.

As of October 2023, 339 radioactive drugs are in clinical trials or under regulatory review globally, including 232 diagnostic and 107 therapeutic agents. Most are in early-stage development, with 293 in Phase I, Phase I/II, or Phase II. As research progresses, more drugs are expected to enter Phase III.

China's radioactive drug industry began developing in the 1950s when large-scale nuclear reactor construction dramatically increased radioisotope availability. In 1958, the Institute of Atomic Energy of the Chinese Academy of Sciences built China's first heavy water reactor and first accelerator, pioneering radioisotope and radioactive drug R&D in China [11]. Commonly used radioisotopes such as 131I, 32P, and 24Na were among the first successfully developed. Subsequent development phases established additional production technologies, including 99Mo and 99mTc. Since the 21st century, China's regulatory framework has steadily improved. Recent national policies have actively encouraged radioactive drug innovation and accelerated approval processes to narrow the gap with developed countries. In April 2023, the National Medical Products Administration (NMPA) issued "Opinions on Reforming and Improving the Review and Approval Management System for Radioactive Drugs," explicitly encouraging R&D and reforming review processes, attracting significant industry attention. To promote R&D and scientific regulation, NMPA has issued six technical guidelines by December 2024, including "Technical Guidelines for Clinical Evaluation of Radioactive In Vivo Diagnostic Drugs" and "Technical Guidelines for Pharmaceutical Research on Radioactive Chemical Generic Drugs" [12], plus drug-specific guidelines for 18F-FDG and 18F-sodium fluoride injection. These major events and regulatory policies have ushered China's radioactive drug industry into a new historical stage.

Table: China's Radioactive Drug Policies and Regulations

Date	Issuing Authority	Policy/Regulation
April 2023	National Medical Products Administration	Opinions on Reforming and Improving the Review and Approval Management System for Radioactive Drugs
January 2022	National Medical Products Administration	Notice on Further Strengthening Radioactive Drug Management
August 2021	NMPA General Office, State Administration of Science, Technology and Industry for National Defense	Notice on Doing a Good Job in the Approval and Supervision of Radioactive Drug Production and Distribution Enterprises

Date	Issuing Authority	Policy/Regulation
December 2012	State Food and Drug Administration	Good Manufacturing Practice for Radioactive Drugs (Appendix)
February 2024	Center for Drug Evaluation, NMPA	Technical Guidelines for Pharmaceutical Research on Radioactive Chemical Generic Drugs
January 2024	Center for Drug Evaluation, NMPA	Technical Guidelines for Non-clinical Research on Radioactive Therapeutic Drugs
January 2024	Center for Drug Evaluation, NMPA	Technical Guidelines for Radioactive Labeled Human Mass Balance Studies
February 2023	Center for Drug Evaluation, NMPA	Technical Guidelines for Clinical Evaluation of Radioactive In Vivo Therapeutic Drugs
October 2020	Center for Drug Evaluation, NMPA	Technical Guidelines for Non-clinical Research on Radioactive In Vivo Diagnostic Drugs
December 2024	National Medical Products Administration	Good Supply Practice for Radioactive Drugs (Draft for Comments)
July 2024	NMPA Special Drugs Inspection Center	Guidelines for Inspection of Radioactive Drug Production (Draft for Comments)

The 2020 edition of the Chinese Pharmacopeia includes 30 radioactive drug varieties, comprising 24 radioactive preparations and 6 non-radioactive supporting kits or raw materials [13]. As of October 2023, 42 radioactive drugs have been approved by NMPA, with 22 included in the Category B medical insurance directory and 20 as non-reimbursed products. By clinical use, 24 are diagnostic only, 15 therapeutic only, and 3 for both diagnosis and therapy. Diagnostic agents are primarily PET and SPECT imaging drugs, represented by 18F-FDG and 99mTc-labeled compounds. Therapeutic agents mainly target tumors, including iodine [125I] seeds, strontium chloride [89Sr], radium chloride [223Ra], and yttrium [90Y] resin microspheres. The three approved diagnostic & therapeutic drugs are all iodine [131I] sodium for thyroid disease diagnosis and treatment. Most approved radioactive drugs in China are generics with long clinical use histories. Since 2020, two innovative therapeutic radioactive drugs have been approved: Bayer's radium [223Ra] chloride for castration-resistant

prostate cancer with symptomatic bone metastases, and Sirtex/Grand Pharmaceutical's yttrium [90Y] resin microspheres for unresectable colorectal liver metastases after standard therapy failure [14,15].

As of October 2023, 32 radioactive drugs are in clinical trials or under review, including 24 diagnostic and 8 therapeutic agents. Unlike approved drugs that are mostly generics, most pipeline drugs are innovative products, with only 8 generics among the 32, demonstrating rapid development of China's original radioactive drugs.

2.3 Development Trends

While traditional imaging modalities like CT and MRI provide clear anatomical localization, they offer poor qualitative value and have obvious clinical limitations. In recent years, SPECT and PET imaging using radionuclides have become increasingly widespread. Technologically, SPECT and PET combine molecular-level lesion detection with precise anatomical localization, and with radionuclide assistance, can non-invasively and accurately generate medical images, effectively improving lesion identification and differential diagnosis accuracy with advantages including high sensitivity, strong specificity, non-invasiveness, and high qualitative value. As SPECT/PET equipment becomes more common in hospitals, radioactive drugs represented by 99mTc have developed rapidly, demonstrating strong economic benefits and market potential. Market data supports this: China's diagnostic and therapeutic radioactive drug market was 2.2 billion RMB in 2017, growing to 3.0 billion RMB by 2021, representing a 9.0% compound annual growth rate (CAGR). Despite lower growth during 2020-2022 due to COVID-19, sales trends have stabilized. With the pandemic's end and policy support, the market will maintain stable growth. From 2021 to 2025, the market is projected to achieve a 32.4% CAGR, reaching 9.3 billion RMB by 2025. From 2025 to 2030, growth will continue at a robust 22.7% CAGR, further expanding the market to 26.0 billion RMB by 2030. The related nuclear medicine equipment market will also grow, with China's nuclear medical equipment market (including radiotherapy devices) projected to maintain 15.3% CAGR from 2021-2025 and 10.3% CAGR from 2025-2030, reaching 25.6 billion RMB by 2030 [16].

However, significant gaps remain compared to global leaders. Future growth drivers include aging population increasing nuclear medicine demand, growth in nuclear medicine departments and professionals, innovative radioactive drug launches, expanding clinical applications, and government policy support. Theranostics will become a key trend, with drug-device integration further advancing the industry. R&D will focus increasingly on precision. As precision medicine concepts spread, more targeted drugs will enter the market. With improving industry chains, domestic supply will gradually increase, expanding market size. Government will invest more funding to accelerate development. Overall, radioactive drugs will become a major pharmaceutical industry direction, with innovative technologies driving progress and creating broad prospects.

3.1 Legal and Regulatory Framework

The special nature of radioactive drugs requires stricter safety and environmental standards than conventional pharmaceuticals, necessitating multi-agency oversight throughout R&D, production, distribution, and use. This covers radioactive drugs, medical devices, isotopes, radiation sources, radiation-emitting devices, radioactive waste recycling, and environmental protection [17]. Regulatory agencies include drug regulatory authorities, environmental protection departments, and nuclear safety regulators, creating a complex and stringent specialized oversight system. Radioactive drug logistics also differ from other pharmaceuticals. Radionuclides have specific half-lives, radiation self-decomposition, and instability, creating demanding logistics requirements. For example, 99mTc (half-life 6 hours) meets examination and safety needs, but production-to-hospital transport presents challenges. The solution involves first producing the longer-half-life precursor 99Mo (half-life 2.7 days), then generating 99mTc as needed. PET, similar to SPECT in using radionuclides and detecting gamma rays, commonly uses 18F (half-life <2 hours), primarily synthesized as 18F-FDG. PET offers better resolution and sensitivity than SPECT, but requires on-site or nearby cyclotrons due to short half-lives, creating unique transportation and distribution requirements for nuclear medicine.

Current Chinese regulations remain inadequate, constraining healthy industry development and affecting public health and environmental protection requirements. Quality control and risk management are also weak links. Due to their special properties, safety risks exist in every link of R&D, production, distribution, and use. China has not yet established a comprehensive quality assurance system across the full life cycle, challenging drug safety and efficacy.

3.2 Technical Barriers and Talent Shortage

Advancing technology creates increasingly severe challenges in radioactive drug R&D, production, distribution, and use. New production technologies, equipment, and more precise quality control methods require continuous updating. High barriers exist for production equipment and technical personnel. Currently, few reactors and cyclotrons produce medical isotopes in China, with insufficient market competition. Radioactive drug manufacturing involves complex nuclear technologies including radioactive tracer techniques, isotope separation, and analytical measurement, requiring extensive experience and qualified nuclear technology professionals, creating barriers for new entrants. Additionally, medical institutions, as primary users, typically have fixed suppliers for safety reasons, and established brands with strong reputations become preferred choices, posing challenges for newcomers. Although China's nuclear medicine industry chain is developing rapidly under policy guidance and market stimulation, upstream production, midstream R&D and distribution, and downstream medical institutions have formed strong industry barriers.

Medical institutions must obtain Radioactive Medical Practice Licenses, Radioactive Drug Use Licenses, and Radiation Safety Licenses to conduct nuclide therapy. Staff must obtain professional qualifications, practice permits, and complete relevant training. As of 2019, China had only 12,500 nuclear medicine professionals: 5,400 physicians, 3,700 technicians, 2,600 nurses, and merely 210 radiochemists—severe shortages. Only 1,148 departments could conduct nuclear medicine diagnosis and treatment, approximately 340 hospitals had nuclide therapy wards, and 736 hospitals performed nuclide therapy, far from meeting patient needs [18-19].

3.4 Production Supply and Distribution

Medical isotopes are primarily obtained through reactor or accelerator irradiation followed by radiochemical separation, with some prepared via generators from precursor nuclides that also require reactor or accelerator production. Reactor irradiation is the most important and common method, producing over 40 medical isotopes (>80% of all types), commonly including 99Mo/99mTc, 125,131I, 89Sr, 32P, 177Lu, 90Y, and 14C. However, due to various reasons, most reactor-produced medical isotopes currently rely on imports, except small quantities of 131I and 177Lu [20]. Domestic isotope production is limited, and innovative separation/purification technologies and GMP production from domestic reactors and accelerators require new technological breakthroughs, restricting medical isotope supply.

Furthermore, foreign countries have established independent nuclear pharmacy networks for production, preparation, and distribution. The U.S. has built diversified production methods and a robust independent nuclear pharmacy network ensuring production and distribution. However, China faces multiple challenges in radioactive drug production and distribution, including limited production capacity under current technical standards for transportation, site cleanliness, and radiation protection, lack of an independent third-party distribution system, and absence of a national, standardized distribution channel.

4.1 Improving Laws and Policy Frameworks

Based on the above analysis, China has not yet established a mature legal and policy framework for full life cycle management of radioactive drugs, affecting safety, efficacy, and environmental protection. Improving relevant laws and establishing a comprehensive management system is crucial for healthy, orderly industry development.

First, regulatory responsibilities for each life cycle link should be clarified. Current oversight involves multiple agencies (NMPA, Ministry of Science and Technology, Ministry of Ecology and Environment), potentially causing unclear responsibilities and weak coordination. A unified coordination mechanism is needed to define agency duties and form regulatory synergy.

Second, referencing international organizations, Europe, the U.S., and Japan, China should formulate and improve regulations tailored to domestic conditions to enhance adaptability and enforceability. Specific clauses on radioactive drug safety and environmental protection should be added, clarifying operational norms and quality control standards for R&D, production, distribution, use, and recycling.

Third, specialized product standards and technical guidelines should be established, covering radiation protection requirements, justification evaluation, optimization of protection, and public dose constraints to ensure safe use and minimal environmental impact.

Additionally, considering the special risks, detailed transportation and distribution standards should be formulated to ensure safe, timely, and effective delivery from manufacturers to end users.

Finally, given the special nature and potential risks, but also considering patient access to innovative drugs, we recommend optimizing review and approval processes alongside regulatory standardization to help patients obtain critical diagnostic and therapeutic products that improve and prolong life.

4.2 Increasing R&D and Talent Investment

The radioactive drug industry chain comprises three segments: upstream—nuclide production via reactors, accelerators, and nuclear waste separation; midstream—R&D, production, and distribution by enterprises; and downstream—medical institutions providing diverse, efficient diagnosis and treatment. R&D and manufacturing enterprises own production technologies, master cutting-edge developments, and can collaborate with nuclear medicine equipment to expand isotope applications and indications. To address current and future needs, China must substantially invest in technology R&D to expand upstream production and break the bottleneck of limited domestic isotope production, while encouraging enterprises to establish full life cycle quality assurance systems to enhance R&D capabilities and management levels, breaking industry barriers.

Talent is key to technological progress and industrial upgrading. Radioactive drug R&D, production, distribution, and use require profound theoretical knowledge and extensive practical experience. Increasing talent investment provides intellectual support for R&D and production, facilitates international exchange, and enhances global competitiveness. Since radioactive drug R&D involves nuclear physics, medicinal chemistry, pharmacology, clinical medicine, and other fields, research institutions, enterprises, and regulators must establish robust R&D teams forming interdisciplinary research synergy.

Therefore, increasing R&D and talent investment is crucial for breaking current development bottlenecks and enhancing international competitiveness to meet clinical needs.

4.3 Establishing Production and Distribution Systems

Chinese radioactive drug enterprises face numerous challenges in production and distribution. Establishing robust systems and enhancing market competition and risk awareness is essential for maintaining competitiveness and addressing potential risks.

First, heightened market competition awareness requires continuous adaptation to market changes. With international regulatory alignment and globalized registration processes, enterprises must adopt global perspectives and actively expand internationally. As foreign manufacturers enter, domestic competition intensifies, requiring continuous product innovation, quality improvement, and service optimization to maintain market share.

Second, strengthened risk awareness is key to sustainable development. Due to their special nature, safety and ethical issues are major risks. Enterprises should establish comprehensive risk management systems covering product quality, production safety, distribution channels, market dynamics, and policy regulations. Risk early-warning mechanisms enable timely responses to market changes and policy adjustments.

Furthermore, enterprises should enhance internal management and organizational responsiveness through optimized structures, improved internal controls, and upgraded employee capabilities. Cross-departmental communication mechanisms ensure rapid information flow and efficient decision-making. Talent development and team building through training and incentives stimulate innovation and enthusiasm.

Finally, China must advance nuclear pharmacy construction, strengthen management of production and distribution enterprises, guide establishment of national, standardized distribution channels, and utilize modern information technology to improve management and response speed, thereby enhancing industry service levels and competitiveness.

4.4 Active International Cooperation and Exchange

China should actively participate in international cooperation and exchange to learn from advanced experiences and enhance competitiveness. In today's globalized world, radioactive drug R&D and application is a multinational endeavor. To gain international market position, China needs not only technological innovation and industrial upgrading but also advanced international experience in full life cycle management.

First, international cooperation brings advanced technology and management experience. Partnerships with foreign research institutions and manufacturers can introduce advanced production equipment, management systems, and quality control systems to improve product quality, efficiency, and reduce costs.

Second, international cooperation enhances innovation capacity. Exchange in-

troduces advanced concepts and creative thinking, bringing new momentum to domestic R&D. International collaboration can introduce new equipment and technologies or incorporate innovative elements into R&D, improving product innovation and competitiveness.

Third, active participation helps Chinese enterprises integrate into global markets. International cooperation projects establish connections for product export and international marketing. Compliance with international rules and standards during cooperation builds brand reputation and expands market access.

Finally, international exchange promotes improvement of domestic laws and regulations. Learning from international management experience through comparative studies can inform domestic regulatory improvements, enhancing scientific and systematic oversight while elevating internationalization of drug regulation.

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