Notice of the Ministry of Industry and Information Technology and Nine Other Departments on Issuing the 15th Five-Year Plan for the Development of the Pharmaceutical Industry[1]

Authorities: **Ministry of Industry and Information Technology and nine other departments (listed below).**

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To the competent departments of industry and information technology, development and reform, natural resources, agriculture and rural affairs, commerce, health, emergency management, healthcare security, traditional Chinese medicine and drug regulation of all provinces, autonomous regions, municipalities directly under the Central Government, cities specifically designated in the state plan, and the Xinjiang Production and Construction Corps:

The 15th Five-Year Plan for the Development of the Pharmaceutical Industry is hereby issued to you. Please implement it conscientiously in light of local conditions.

Ministry of Industry and Information Technology
National Development and Reform Commission
Ministry of Natural Resources
Ministry of Agriculture and Rural Affairs
Ministry of Commerce
National Health Commission
Ministry of Emergency Management
National Healthcare Security Administration
National Administration of Traditional Chinese Medicine
National Medical Products Administration

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[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

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15th Five-Year Plan for the Development of the Pharmaceutical Industry

This Plan is formulated in accordance with the Outline of the Fifteenth Five-Year Plan for National Economic and Social Development of the People's Republic of China, to implement the decisions and arrangements of the CPC Central Committee and the State Council, fulfill the strategic tasks of building China into a manufacturing powerhouse and advancing the Healthy China initiative, and promote the high-quality development of the pharmaceutical industry.

I. General Requirements

Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, the guiding principles of the 20th CPC National Congress and all plenary sessions of the 20th CPC Central Committee shall be thoroughly implemented, and the arrangements of the Fourth Plenary Session shall be conscientiously carried out. The new development philosophy shall be applied fully, accurately and comprehensively, and the establishment of a new development pattern shall be accelerated. With the goal of substantially achieving new industrialization, development and security shall be coordinated. High-quality development shall be the overarching theme, people's health the central focus, and the cultivation and development of new quality productive forces the key priority. Innovation shall be activated as the core driving force; a resilient and secure foundation shall be established; the enabling role of integrated digital and intelligent technologies shall be deepened; new approaches to precision diagnosis and treatment shall be advanced; efficiency improvements and transformation shall be promoted; value-creation capabilities shall be strengthened; inclusive access shall be improved; and open, mutually beneficial cooperation shall be expanded. These efforts shall establish a strong material and technological foundation for comprehensively meeting health needs throughout the life cycle and advancing the Healthy China initiative in all respects.

By 2030, China shall maintain a leading global position in biopharmaceutical research, development and application, fully unlock the benefits of innovation-driven development, and achieve systematic breakthroughs in key core technologies in priority areas. Digital and intelligent technologies shall deliver tangible benefits across the entire industrial chain, and the precision medicine system shall effectively support comprehensive prevention and treatment of major diseases. The ecosystem for coordinating production factors shall become increasingly mature, and the scope for industrial development shall continue to expand. Robust manufacturing and supply safeguards shall be in place, core competitiveness and international influence shall increase substantially, and the industry shall become deeply integrated into global pharmaceutical innovation networks. The biopharmaceutical industry shall accelerate its development into a national emerging pillar industry, continuously safeguard and improve people's health and well-being, and strongly support the implementation of the manufacturing powerhouse and Healthy China strategies. It shall provide a solid industrial contribution to safeguarding national security and jointly building a global community of health for all.

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Box 1. Indicative Targets for Pharmaceutical Industry Development during the 15th Five-Year Plan Period

No.	Indicator	2030	Annual average / cumulative
1	Revenue of pharmaceutical industrial enterprises above the designated size (RMB trillion)	≥3.5	-
2	Average R&D expenditure intensity of listed pharmaceutical industrial enterprises (%)	-	≥10
3	Number of investigational new drug pipeline assets entering clinical trials for the first time	Among the world leaders	-
4	Global share of first-in-class (FIC) drugs (%)	≥25	-
5	Number of innovative drugs approved for marketing	Among the world leaders	-
6	Number of innovative medical devices approved for marketing	-	[≥200]
7	Growth rate of the size of the innovative drug industry (%)	-	≥20
8	Number of pharmaceutical industrial enterprises with annual revenue exceeding RMB 10 billion	50	-
9	Number of pharmaceutical industrial parks at the RMB 100 billion scale	20	-
10	Number of products with annual global sales exceeding USD 1 billion	≥5	-

Notes: (1) Figures in square brackets represent cumulative totals over five years. (2) The statistical scope used to calculate the share of first-in-class (FIC) drugs in the global innovative drug pipeline includes drugs in Phase I, II and III clinical trials, drugs at the new drug application stage (NDA/BLA), and drugs approved for marketing. It excludes preclinical products and products whose development has been terminated or discontinued.

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II. Priority Tasks

(1) Steering the Industry towards Innovation and Higher Quality and Building New Drivers of Innovation-led Development

1. Strengthening Original Innovation Capabilities

Priority shall be given to major infectious diseases, major chronic diseases, rare diseases, pediatric medicines and other key areas. Enterprises' central role in innovation shall be reinforced, and research and development of innovative drugs and medical devices in China shall be accelerated towards first-in-class, breakthrough and disruptive innovation. Pharmaceutical industrial enterprises shall be supported in pursuing frontier pharmaceutical science and technology and developing first-in-class (FIC) and best-in-class (BIC) drugs involving new targets, new mechanisms and new drug types. The research, development and application of advanced medical devices at the technological frontier shall be accelerated.

Box 2. Priority Areas and Products for Innovation

1. Chemical Drugs

Drugs with new targets and new mechanisms of action. Priority shall be given to developing drugs acting on targets traditionally considered undruggable; drugs directed at new targets identified through genomics, proteomics, spatial omics and other approaches; drugs targeting host factors associated with major diseases; and drugs acting through allosteric modulation, epigenetic and transcriptional regulation, regulation of RNA function, or microenvironment remodeling.

New drug modalities. Priority shall be given to developing oligonucleotide drugs such as small interfering RNA (siRNA) and antisense oligonucleotides (ASO); targeted protein degradation drugs, including proteolysis-targeting chimeras (PROTACs) and molecular glues; novel peptide and oral cyclic peptide drugs; peptide-drug conjugates (PDCs); and peptide- or small-molecule-radionuclide conjugates.

Novel delivery systems and technologies to optimize druggability. Priority shall be given to developing brain-targeted delivery systems for chemical drugs and delivery systems responsive to pathological microenvironments, including pH-responsive and enzyme-specific release systems. Priority shall also be given to nanomedicine technologies, including liposomes and polymeric nanoparticles, technologies to enhance oral absorption, and sustained-release, controlled-release and long-acting technologies.

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2. Traditional Chinese Medicines

New traditional Chinese medicines. Development of innovative medicines shall be intensified in disease areas and stages of treatment where traditional Chinese medicine offers advantages. Modern technologies shall be used to transform preparations made by medical institutions and experiential prescriptions of renowned senior traditional Chinese medicine practitioners into innovative traditional Chinese medicines in modern dosage forms. New technologies and methods shall be used, with priority given to natural medicines that combine systemic regulation with targeted intervention and have clearly defined constituents and mechanisms of action.

Classical prescriptions. Based on the Catalogue of Ancient Classical Prescriptions, research shall cover the full chain from Chinese medicinal materials and prepared slices to reference samples and preparations, with a view to developing compound traditional Chinese medicine preparations based on ancient classical prescriptions.

Ethnic medicines. Focusing on the distinctive features of Tibetan, Mongolian, Uygur and other ethnic medical traditions and the diseases for which they offer advantages, characteristic medicinal resources and proven prescriptions shall be explored. Priority shall be given to innovative drugs, distinctive compound preparations and preparations specifically intended for specialist use.

3. Biological Products

Antibody and recombinant protein drugs. Priority shall be given to developing antibodies against new targets and bispecific or multispecific antibodies; innovative products that combine enhanced tumor targeting with immune activation; long-acting antibodies and recombinant protein drugs; recombinant fusion proteins; recombinant proteins for enzyme replacement therapy; highly targeted bispecific or multispecific antibodies with masking peptides that are specifically cleaved in the tumor microenvironment; and antibodies and recombinant proteins targeting the complement system.

Next-generation conjugated drugs. Priority shall be given to developing bispecific or multispecific antibody-drug conjugates (ADCs); highly targeted ADCs using novel payloads, including dual payloads, and linkers enabling tumor-microenvironment-specific release; antibody- or protein-radionuclide conjugates (RDCs); and antibody-oligonucleotide conjugates (AOCs).

Cell and gene therapy drugs. For solid tumors, autoimmune diseases, genetic diseases and other conditions, priority shall be given to novel chimeric antigen receptor T-cell (CAR-T) therapies directed at new targets, universal CAR-T therapies, CAR-T therapies using in vivo gene editing, and induced pluripotent stem cell (iPSC) therapies. Priority shall be given to delivery systems such as adeno-associated virus (AAV) vectors for in vivo gene delivery and lipid nanoparticles (LNPs) for in vivo delivery of nucleic acid drugs.

Novel vaccines. Priority shall be given to mRNA vaccines for new indications such as respiratory syncytial virus (RSV) infection and herpes zoster; new recombinant vaccines to

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replace conventional vaccines; combination vaccines; vaccines using new routes of administration; and new vaccine adjuvants.

4. Medical Devices

Implantable and interventional devices. Priority shall be given to coronary stents with controllable degradation rates, cardiac pacemakers, neurointerventional microcatheters and microguidewires, and drug-eluting peripheral arterial stents. Priority shall also be given to breakthroughs in titanium alloy/titanium nitride surface nanomodification, rapid precision 3D printing and related technologies, for application to regenerative medicine materials such as 3D-printed implants and tissue repair materials.

In vitro diagnostic devices. Priority shall be given to technologies and products for novel molecular diagnostics, single-cell sequencing, early cancer screening and genetic testing for rare diseases.

Intelligent medical devices. Priority shall be given to AI-assisted diagnostic products and key components, including high-end computed tomography (CT), magnetic resonance and multimodal AI pathology systems; therapeutic equipment, including high-end radiotherapy systems, multimodal AI surgical navigation and positioning systems, and specialized, lightweight robots for minimally invasive interventional surgery; home-use medical devices, including AI-driven closed-loop insulin pumps, non-invasive continuous blood pressure/blood glucose monitoring devices and multiparameter home heart-failure management systems; and rehabilitation devices, including exoskeleton robots, brain-computer-interface-driven exoskeletons and AI gait analysis systems.

2. Fully Harnessing Industrial Innovation Platforms

Pharmaceutical industrial enterprises shall be supported in deepening cooperation with national laboratories and innovation platforms such as national technology innovation centers, national manufacturing innovation centers, national industrial technology engineering centers and national clinical research centers. Clinical application validation and evaluation shall be strengthened, linking basic pharmaceutical research with the translation of research outcomes. Specialized service-oriented pharmaceutical manufacturing shall be developed, and platforms providing pharmaceutical research, development and manufacturing services shall be strengthened. Validation, translation and industrial application of key technologies for new modalities, including novel antibodies, conjugated drugs, oligonucleotide therapeutics and peptide drugs, shall be accelerated. Technological preparedness for vaccines and therapeutic drugs against emerging and unexpected major infectious diseases shall be strengthened.

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3. Actively Cultivating and Expanding Innovative Drug and Medical Device Industries

Research, development, manufacturing and wider application of innovative drugs and medical devices shall be intensified in priority areas including cancer, autoimmune diseases, metabolic diseases, cardiovascular diseases and neurological diseases. The emergence of blockbuster products capable of driving expansion of the industry shall be accelerated. Platforms shall be established to match the supply of and demand for medicines for children, older people, patients with rare diseases and other groups, and the development and application of products in appropriate dosage forms and strengths shall be accelerated. Real-world studies shall be encouraged for evaluation throughout the drug life cycle. Comprehensive clinical evaluation, and the analysis and application of its findings, shall be strengthened.

4. Accelerating the Development of Frontier Technologies and Products

Interdisciplinary integration and the provision of frontier technologies shall be strengthened. Joint research to overcome key technological challenges by pharmaceutical industrial enterprises, universities, research institutes, medical institutions and other entities shall be supported. The use of artificial intelligence, quantum computing, supercomputing, computational medicine and other new technologies in drug research and development shall be accelerated. New drug and medical device manufacturing models, including manufacturing beyond conventional limits, pharmaceutical manufacturing in space and biomanufacturing, shall be explored. Applications of gene editing, precision molecular delivery, cell programming and regulation, advanced omics, next-generation brain-computer interfaces and other frontier technologies shall be deepened. Breakthroughs shall be pursued in key technologies such as synthetic artificial living systems, organoids and organ-on-a-chip systems, universal cell therapies, complex regenerated organs, theranostic radiopharmaceuticals and organs for xenotransplantation, to cultivate new sources of growth.

Box 3. Priority Frontier Technologies

1. Basic research stage. Quantum generative AI technologies for drug molecule design; dual-modal prediction of biomacromolecular structure and sequence; RNA three-dimensional structure prediction and functional analysis; digital data storage in DNA; digital twins across pharmaceutical scenarios; precision-gene-editing-based breeding of Chinese medicinal plants; biomolecular phase separation and targeted interventions in condensates; development and in vivo delivery of novel gene-editing systems; biomimetic nanovaccines; microenvironment-responsive masking peptides and prodrug activation; and extraction and purification of low-abundance, high-purity precursor radionuclides for medical use.

2. Technology translation stage. Clinical cohort data analysis and drug target discovery based on multi-omics big data; AI-driven drug evaluation using organoids and organ-on-a-chip systems; biological substitution and sustainable utilization of rare and endangered medicinal resources; precision efficacy evaluation based on the dynamic

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evolution of traditional Chinese medicine syndromes; spatiotemporal dynamic analysis of the multi-target mechanisms of traditional Chinese medicines; efficient discovery of active molecules in traditional Chinese and natural medicines; large-scale production of viral vectors for gene therapy; macromolecule-conjugated degraders; cell-based medicinal products derived from human induced pluripotent stem cells; and high-power target systems for multiple radionuclides.

3. Industrial maturation stage. Cooperative catalytic synthesis and continuous-flow manufacturing; pharmaceutical cocrystals and crystal-form engineering; chemical modification of RNA drugs (mRNA, siRNA and ASO); synthetic-biology-driven large-scale production of natural medicines; fully automated, highly sensitive molecular diagnostics; automated synthesis and Good Manufacturing Practice (GMP) manufacturing of beta-emitting radiopharmaceuticals; full-process quality control and evaluation of innovative alpha-emitting radiopharmaceuticals; and radiolabeling and biological evaluation of novel radiopharmaceuticals.

(2) Strengthening Foundations and Competitive Advantages and Establishing a Resilient and Secure System

5. Consolidating the Industrial Foundation

Mechanisms for assessing and responding to security risks in pharmaceutical industrial and supply chains shall be improved, and monitoring and early warning for priority products and key links in the industrial chain shall be strengthened. Relevant pharmaceutical industrial enterprises shall be supported in joint upstream and downstream research to achieve breakthroughs in key technologies involving pharmaceutical excipients, high-end pharmaceutical manufacturing equipment and consumables, instruments and reagents, raw materials and industrial software. Industrial pilot-scale platforms shall be strengthened to accelerate the translation of scientific and technological achievements and iterative technological upgrades, linking technology research and development, functional validation and large-scale application of innovative products. The establishment of key data platforms, including bioinformatics centers and industrial infrastructure for life and health big data, shall be supported.

Box 4. Foundational Industrial Technologies and Products

1. High-end Pharmaceutical Excipients and Packaging Materials

High-end pharmaceutical excipients. Priority shall be given to matrix materials for oral sustained-release and controlled-release preparations; novel stimulus-responsive and actively targeted materials; excipients specifically intended for advanced preparations such as biological and nucleic acid drugs; excipients for novel transdermal preparations; excipients for inhalation preparations; and excipients specific to traditional Chinese medicines.

Pharmaceutical packaging materials. Priority shall be given to cyclic polyolefins (including COC and COP), fluoropolymer film-coating materials, heat-shrinkable elastomers (TPE) and

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other materials; packaging materials and formats suitable for traditional Chinese medicine preparations; self-administration devices; wearable pharmaceutical packaging and devices; and internal/external spray-coating and surface-treatment materials for drug containers and components made of aluminum, glass and other materials.

2. Raw Materials

Raw materials for high-end implantable and interventional medical devices. Priority shall be given to medical-grade polyurethane, polytetrafluoroethylene, polyetheretherketone, polysulfone/polyethersulfone, ultrathin titanium-nickel strips and wires, platinum alloy wires, zirconium-niobium alloys, biodegradable medical magnesium/zinc alloys, high-purity zirconia, and hydrophilic lubricating, antimicrobial and anticoagulant coatings.

Raw materials and consumables for biological drug manufacturing. Priority shall be given to novel serum-free culture media; chromatography resins for the separation and purification of different biological products; and membrane filtration materials for depth filtration, ultrafiltration and nanofiltration.

3. Manufacturing Process Systems

Manufacturing process systems for active pharmaceutical ingredients and preparations. Priority shall be given to microchannel reactors, nucleic acid synthesizers, novel crystallizers, high-containment isolators, membrane separation systems, high-end bioreactors and core components, disc-stack centrifuges, fully automated single-use chromatography/multicolumn continuous chromatography systems, equipment for advanced preparations such as micro- and nanoformulations and transdermal patches, and high-speed integrated aseptic blow-fill-seal (BFS) production lines.

Medical device manufacturing process systems. Priority shall be given to high-end five-axis machining centers, specialized four-axis precision-forming machine tools for interventional devices, customized 3D bioprinting equipment, specialized plasma-spraying equipment for surface modification, precision etching machines for microfluidic chips, and high-precision optical assembly, alignment and inspection systems.

4. Pharmaceutical Industrial Software

Drug research and development. Priority shall be given to laboratory information management systems, computer-aided drug design, and AI-based drug discovery and design.

Manufacturing control. Priority shall be given to industrial control systems incorporating Good Manufacturing Practice for Drugs (GMP), including manufacturing execution systems, advanced planning and scheduling systems, process analytical systems, supervisory control and data acquisition systems, and distributed control systems.

Quality assurance. Priority shall be given to drug and medical device quality management systems, quality review systems, electronic batch record systems, and process-trend prediction and deviation analysis systems.

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6. Consolidating Competitive Advantages

An initiative for efficient substitution of off-patent drugs shall be implemented. The systematic development and wider application of generic drugs and biosimilars shall be advanced, and rapid iterative upgrades in technologies, dosage forms and processes shall be supported to substantially improve access to clinically valuable medicines. Market competitiveness and control over the chemical active pharmaceutical ingredient industrial chain shall be strengthened, and continuous, intelligent and green manufacturing shall be enhanced. Traditional Chinese medicine industrial enterprises shall be supported in preserving traditional knowledge while pursuing innovation and strengthening the quality and brand advantages of major traditional Chinese medicine products. Innovative traditional Chinese medicines shall be actively developed. Evaluation systems consistent with the principles and characteristics of traditional Chinese medicine shall be improved, and pathways for translating classical prescriptions and medical institution preparations into products manufactured at scale shall be streamlined.

Box 5. Manufacturing Technologies Offering Competitive Advantages

1. Green manufacturing technologies for active pharmaceutical ingredients. Priority shall be given to enzyme catalysis, electrochemical reactions, photochemical synthesis, biosynthesis and continuous synthesis; replacement or reuse of precious-metal catalysts; substitution of toxic and hazardous raw materials, materials with high volatile organic compound (VOC) content and materials with high photochemical reactivity; wastewater treatment using advanced oxidation and membrane bioreactors; treatment of highly concentrated refractory wastewater; efficient treatment of waste gases containing volatile organic compounds; and resource recovery, harmless treatment and evaluation of liquid and solid waste residues.

2. Key technologies and processes for traditional Chinese medicines. Priority shall be given to artificial propagation and breeding of endangered medicinal resources, selective breeding of Chinese medicinal materials, ecological cultivation and animal husbandry for medicinal resources, intelligent processing of Chinese medicinal materials, continuous manufacturing of traditional Chinese medicines, and quality control throughout the industrial chain. Breakthroughs shall be achieved in optimizing the druggability of natural active molecules; elucidating the material basis of compound traditional Chinese medicines; identifying quality markers; evaluating quality-efficacy relationships; and controlling batch-to-batch consistency.

3. Processes for complex advanced chemical drug preparations. Priority shall be given to liposomal targeted delivery, long-acting sustained release through microspheres and implants, nanocrystal-enhanced solubility, transdermal microneedles, stimulus-responsive drug release, oral sustained and controlled release, mucosal delivery, 3D-printed preparations, and continuous intelligent manufacturing.

4. Processes for manufacturing advanced biological drugs. Priority shall be given to cell-line development, perfusion culture, continuous-flow chromatography, viral vector

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production, site-specific ADC conjugation, extrahepatic targeted delivery of oligonucleotide therapeutics, mRNA-LNP encapsulation, CAR-T expansion, fully closed automated cell processing, circular RNA preparation and exosome-mediated delivery.

5. Advanced medical device manufacturing processes and technologies. Priority shall be given to core processes such as ultraprecision micro- and nanomachining, integrated forming of interventional products, and high-precision replication of biomimetic structures; and functional treatments such as highly biocompatible surface modification and anticoagulant and anti-infective coatings. Process bottlenecks shall be overcome in flexible forming of minimally invasive interventional devices, high-precision drawing of thin-walled tubing and precision polishing of complex internal lumens.

7. Cultivating New Drivers of Development

Priority industrial chains with competitive advantages shall be developed for biosimilars, peptide drugs, oligonucleotide therapeutics, advanced preparations and in vitro diagnostic products. Industrialization of priority products shall be promoted, internationally leading enterprises in specialized segments shall be cultivated, and industrial clusters shall be developed. Pharmaceutical industrial enterprises shall be encouraged to focus on advanced preparations involving sustained and controlled release, targeted delivery and new routes of administration, and to develop outstanding products with strong market acceptance and significant clinical value. Iterative upgrades of in vitro diagnostic products shall be accelerated, application scenarios expanded, and testing and inspection service systems improved.

(3) Continuously Improving Quality and Efficiency and Setting New Benchmarks for Digital and Intelligent Transformation

8. Deepening AI-enabled Upgrading

Pharmaceutical industrial enterprises shall be supported in working with medical institutions, research institutes and pharmaceutical research and development service providers to establish high-quality datasets for the pharmaceutical industry, create trusted data spaces for pharmaceuticals and healthcare, facilitate the circulation and use of pharmaceutical and health data, and accelerate the development of pharmaceutical domain-specific large models and intelligent agents. High-value AI applications shall be developed in drug discovery, clinical research, process optimization, quality management, distribution and use, and intelligent regulation, accelerating AI-driven transformation in pharmaceutical research and development and manufacturing management.

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9. Promoting Digital and Intelligent Transformation

High-value application scenarios shall serve as the starting point for collaborative development of integrated digital and intelligent pharmaceutical solutions, technologies and products. Industrialization of core components, including high-end sensors for testing and online analyzers, shall be accelerated. The guiding role of standards and specifications shall be strengthened, and the public service system supporting digital and intelligent transformation shall be improved. Service platforms, including centers promoting digital and intelligent transformation of the pharmaceutical industry and digital transformation of manufacturing, shall be used to advance research into common technologies and their wider application. Technical services, including hardware/software compatibility verification and testing and computerized systems validation (CSV), shall be provided across the industry, accelerating improvements in quality management and development performance.

10. Accelerating Green Upgrading

Pharmaceutical industrial enterprises shall be encouraged to use big data, artificial intelligence, the industrial internet and other technologies to strengthen precise monitoring and intelligent control of energy and resource use throughout drug manufacturing, and continuously improve the coordinated development of digitalization and environmental sustainability. Enterprises shall be guided in meeting requirements for green factories, green industrial parks and green supply chains. Carbon footprint assessments shall be encouraged in active pharmaceutical ingredients and other sectors. Enterprises handling flammable or explosive hazardous chemicals or explosive dust shall be supported in accelerating digital transformation to improve inherent safety.

Box 6. Developing High-value Applications of AI in Pharmaceuticals

1. Intelligent target screening and drug discovery. Priority shall be given to developing and deploying AI-enabled target screening, drug molecule design and optimization, virtual compound screening, candidate drug characterization, animal-model data mining, mining of human-use experience data for traditional Chinese medicines and research into decision models, integrated laboratory data management, and assistance with review and scientific assessment of clinical trial protocols.

2. Intelligent pharmaceutical manufacturing and quality management. Priority shall be given to developing and deploying AI-based systems for automatic data collection and traceability throughout pharmaceutical manufacturing, and intelligent AI platforms providing real-time early warning and closed-loop control for critical quality attributes.

3. Intelligent use of medicines and health management. Priority shall be given to intelligent medication guidance and assisted prescription review. Digital twins and AI predictive models shall be combined to explore highly realistic virtual patient models and disease-progression model systems, supporting clinical diagnosis and treatment, real-world research and personalized health management.

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4. Intelligent regulation of drug and medical device manufacturing and distribution. Priority shall be given to large models and intelligent agents for the review, approval and inspection of drugs, cosmetics and medical devices, effectively supporting frequent tasks such as intelligent product classification, task allocation, dossier review, knowledge retrieval, issue identification, report generation, and issuance and delivery of certificates. Data throughout the life cycle, including research and development, manufacturing, distribution and use, shall be integrated to ensure quality and safety control throughout the life cycle of drugs and medical devices.

5. Intelligent real-world research and post-marketing evaluation. Platforms for real-world data research and application shall be established. The systematic and standardized collection of clinical real-world use data on drugs and medical devices through AI and other technologies shall be supported. Such data shall be incorporated into trusted data spaces for in-depth linkage, mining and analysis, supporting clinical evaluation throughout the product life cycle in accordance with applicable laws and regulations.

(4) Responding to Technological Advances and Developing New Approaches to Precision Diagnosis and Treatment

11. Developing Drugs and Medical Devices for Precision Prevention

The integration of genetic testing and biogenetic technologies with disease prevention systems shall be advanced. Pharmaceutical industrial enterprises shall be supported in developing novel vaccines, precision nutrition products, targeted intervention products and intelligent prevention solutions, and in improving product research and development and manufacturing quality control systems. Demand-driven development shall be strengthened, and early screening and prevention of major conditions such as genetic diseases, birth defects, cancer and cardiovascular diseases shall be reinforced. Enterprises shall be guided in cooperating with professional health management institutions and intensifying development of health management products.

12. Expanding the Precision Diagnostics Industry

Priority shall be given to high-throughput gene sequencing, microfluidics and highly sensitive biological detection. Integration and upgrading across in vitro diagnostics, medical imaging, pathological diagnosis, molecular diagnostics and multi-omics testing shall be promoted, and industrialization of innovative diagnostic products shall be accelerated. Quality control, clinical evaluation and standards systems for precision diagnostic products shall be improved. Medical institutions with the necessary capabilities shall be encouraged to develop precision diagnostic centers and strengthen cooperation with relevant enterprises. Interconnection, sharing and joint use of diagnostic and treatment data shall be promoted. The integration of precision diagnostic technologies with digital health and artificial intelligence shall be accelerated to improve precision diagnosis of rare diseases, cancer, genetic diseases and other conditions.

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Box 7. Priority Precision Medicine Technologies and Products

1. Products for precision early cancer screening and diagnosis. Priority shall be given to combined multi-omics testing involving genomics, metabolomics and proteomics. Focusing on early screening for multiple cancers, barriers to the broad application of key technologies such as digital liquid biopsy and methylation testing shall be overcome to improve early detection rates. Priority shall be given to tumor molecular subtyping and specific-target detection products, and the clinical application of combined multitarget detection technologies based on circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), exosomes and related approaches shall be promoted. AI-assisted imaging diagnosis and multimodal image fusion shall be developed to achieve precise lesion localization and characterization. Research and development of molecular imaging probes for nuclear medicine shall be strengthened; novel positron emission tomography (PET) and single-photon emission computed tomography (SPECT) tracers shall be developed; and radionuclide-based theranostic products shall be developed and applied.

2. Precision diagnostic products for major chronic diseases. For early detection and precision diagnosis of cardiovascular and cerebrovascular diseases, metabolic disorders, neurodegenerative diseases and other chronic conditions, priority shall be given to novel in vivo detection technologies, including microneedle and sweat sensing, to enable continuous, non-invasive monitoring of physiological indicators. Priority shall be given to precise blood-lipid subtyping and testing products for genetic susceptibility. For Parkinson's disease, Alzheimer's disease and other neurodegenerative conditions, biomarker-based targeted intervention products and early screening technologies shall be developed to enable early warning and intervention.

3. Precision testing products for maternal, infant and child health. Priority shall be given to NIPT 2.0 (next-generation non-invasive prenatal screening), carrier screening products for hereditary diseases and broad-spectrum preventive vaccines. The use of next-generation gene sequencing products in birth-defect prevention and control shall be promoted. New methods for non-invasive prenatal testing of monogenic hereditary diseases based on high-throughput sequencing shall be developed to expand the range of conditions screened. Rapid precision testing products shall be developed for priority birth defects, including neonatal inherited metabolic disorders and gene-deletion disorders, to enable precise diagnosis and early prevention of genetic diseases, reduce birth-defect risks, and improve maternal and infant health protection.

4. Precision infection prevention and diagnostic products for public health. Priority shall be given to products for early warning of infection and immune intervention, establishing public health prevention and control systems and improving full-chain prevention and control of communicable and infectious diseases. Point-of-care testing (POCT) products shall be developed. Breakthroughs in core technologies for precise pathogen identification, including rapid nucleic acid amplification, microfluidic chips and CRISPR, shall enable rapid on-site testing. Broadly applicable multiplex pathogen detection products and rapid antimicrobial-resistance gene detection products shall be developed to

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improve early detection and rapid response to emerging and unexpected infectious diseases.

13. Establishing an Industrial Ecosystem for Precision Treatment

Pharmaceutical industrial enterprises shall be supported in extending their activities across the full testing-diagnosis-treatment chain and establishing portfolios of precision treatment products based on targets and disease subtypes. Enterprises shall be encouraged to strengthen coordinated cooperation among industry, academia, research and clinical users with medical institutions, research institutes and other entities. Research, development and industrialization of precision treatment products for major diseases shall be accelerated, including targeted drugs, antibody drugs, cell and gene therapies, innovative traditional Chinese medicine preparations, and minimally invasive interventional devices.

(5) Unlocking the Potential of the Production-factor Ecosystem and Achieving New Efficiency Gains

14. Streamlining Pathways for Efficient Clinical Translation

Pharmaceutical industrial enterprises shall be supported in joining universities, research institutes and medical institutions to establish translational medicine consortia and clinical resource-sharing networks, effectively linking target discovery and drug screening with clinical needs. Translational medicine centers and non-clinical research platforms shall be established in key industrial parks to provide pharmacodynamic evaluation, toxicological research and other services. Research-oriented hospitals shall be supported in leading the establishment of high-standard clinical trial institutions. Clinical trial protocols, ethics review and related procedures shall be optimized to further shorten trial initiation timelines. Unified hospital information system (HIS) standards shall be supported, and digital transformation of clinical trials and networked links with review and inspection processes shall be encouraged. Enterprises shall be supported in establishing technology transfer institutions and specialized service teams to improve the efficiency of translating innovative outcomes from the laboratory to the clinical stage.

15. Improving Systems for Efficient Engineering Scale-up

Focusing on manufacturing process validation needs for antibody drugs, recombinant protein drugs, cell and gene therapies and other fields, pharmaceutical industrial enterprises and specialized institutions shall be supported in establishing proof-of-concept and pilot-scale validation platforms. Third-party institutions shall be encouraged to establish pilot-scale facilities and make key equipment and production-line resources available to small and medium-sized enterprises. Enterprises shall be supported in optimizing processes and validating scale-up in key stages such as cell culture, purification and separation, and formulation processes, to improve product stability and batch-to-batch consistency. Upstream equipment, raw-material and excipient suppliers shall be guided in collaborative research with pharmaceutical manufacturers to strengthen support for engineering scale-up and large-scale manufacturing.

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16. Establishing Efficient Industrial Coordination

Leading pharmaceutical industrial enterprises shall fully exercise their role in driving the specialized, refined, distinctive and innovative development of small and medium-sized enterprises, and manufacturing champions in specialized segments shall be cultivated. Generic drug, biosimilar and active pharmaceutical ingredient manufacturing shall be encouraged to concentrate in enterprises with economies of scale and leading manufacturing quality standards. Key industrial parks shall be used to cluster research and development, pilot-scale operations and manufacturing. Public service platforms and specialized incubators shall be established to provide small and medium-sized enterprises with testing, certification, registration application and other services. Initiatives to cultivate new industrial sectors in national high-tech zones shall be undertaken, developing priority emerging biopharmaceutical sectors. World-class pharmaceutical industrial clusters shall be promoted in the Beijing-Tianjin-Hebei region, the Yangtze River Delta and the Guangdong-Hong Kong-Macao Greater Bay Area. Leading domestic pharmaceutical industrial clusters with distinctive strengths shall be established to improve overall efficiency and development at scale. Coastal resource advantages shall be harnessed, with coordinated development of full-chain innovation systems linking resources, science and technology, industry and applications, to create clusters for marine-derived medicines and functional products.

Box 8. Cultivating Competitive Industrial Clusters

1. Biopharmaceutical clusters in Beijing-Tianjin-Hebei and other Bohai Rim areas. Building on complementary resource strengths in Beijing, Tianjin, Hebei, Shandong, Liaoning and other Bohai Rim provinces and municipalities, a new industrial pattern shall be established, with Beijing and Tianjin as sources of research and innovation, coordinated regional translation, and large-scale manufacturing in the hinterland. Priorities include innovative small-molecule drugs, cell and gene therapies, high-end medical devices, brain-computer interfaces, modern traditional Chinese medicines, high-end active pharmaceutical ingredients, marine-derived medicines, and high-end service-oriented pharmaceutical manufacturing.

2. Innovative drug and medical device clusters in the Yangtze River Delta. The region's abundant drug research and development and clinical resources and comprehensive manufacturing system shall be harnessed to unlock growth potential and achieve efficient coordination. The region shall become a global launch location for innovative drugs and devices and a preferred location for start-ups founded by scientists, with a continuous flow of world-first innovations, products first launched in China and products first used clinically. Development shall be accelerated in innovative small-molecule drugs, novel antibodies, cell and gene therapies, and high-end medical devices; recombinant protein drugs, high-end active pharmaceutical ingredients and pharmaceutical excipients; and marine-derived medicines, functional products and radiopharmaceuticals.

3. Innovative drug and medical device clusters in Guangdong-Hong Kong-Macao. Drawing on industrial clustering, institutional advantages such as the mechanism permitting

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use of Hong Kong- and Macao-approved drugs and medical devices, coordination among Guangdong, Hong Kong and Macao, and the Greater Bay Area's openness and concentration of international resources, a globally renowned high-end medical device research and development center and a domestically leading, internationally first-class pharmaceutical industrial hub shall be established. Priorities include high-end medical devices, high-end active pharmaceutical ingredients, innovative drugs, brain-science and brain-computer-interface products, modern traditional Chinese medicines, and marine-derived medicines and functional products.

4. Chengdu-Chongqing biopharmaceutical clusters. Building on complementary biopharmaceutical resources and industrial coordination in the Chengdu-Chongqing economic circle, the combined strengths of Chengdu in frontier research and clinical translation and Chongqing in high-end device manufacturing and logistics shall be harnessed. A collaborative pattern of research and development in Chengdu and manufacturing in both cities shall be established, prioritizing antibody drugs, gene therapies, high-end imaging equipment, nuclear medicine products, modern traditional Chinese medicines and contract pharmaceutical service (CXO) platforms.

5. Pharmaceutical manufacturing clusters in central China. The location, transport, industrial foundation and cost advantages of the middle reaches of the Yangtze River and Central Plains urban agglomerations shall be harnessed. Manufacturing clusters for chemical drugs, traditional Chinese medicines, biological products and medical devices, together with pharmaceutical logistics centers, shall jointly drive regional development, deepening coordination across research and development, manufacturing and distribution. Priorities include high-end active pharmaceutical ingredients, advanced chemical drug preparations, blood products, medical devices, medical consumables, modern traditional Chinese medicines and pharmaceutical cold-chain logistics.

6. Traditional Chinese medicine and ethnic medicine clusters in border regions. Distinctive strengths in medicinal resource cultivation, ethnic medicine and specialized diagnosis and treatment in Tibet, Inner Mongolia, Xinjiang, Yunnan, Guangxi, Hainan, Jilin and other regions shall be harnessed. Full-chain development covering resource protection, standards formulation, brand development and cross-border cooperation shall be strengthened. An integrated pattern of medicinal materials from authentic producing areas, standardized production and international application shall be established. High-standard production bases for traditional Chinese medicine raw materials and bases for the preservation, innovation and translation of ethnic medicines shall be created. Priorities include high-quality prepared slices of Chinese medicinal materials, ethnic medicine varieties produced exclusively by individual manufacturers, health products derived from substances used as both food and medicine, and tropical marine-derived medicines.

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(6) Advancing Quantity and Quality Together and Expanding Value Creation

17. Deepening the Pharmaceutical Industry's Contribution to Health

Industrial spillover effects shall be harnessed to establish pharmaceutical and health industry ecosystems. Integration with healthy aging services, health tourism, chronic disease wellness and rehabilitation, fitness and recreation, and healthy foods shall be actively promoted to generate new products, business formats and models. Pharmaceutical industrial enterprises shall be supported in developing health-related consumer goods, including products based on substances used as both food and medicine, intelligent health wearables, health foods and foods for special medical purposes (FSMPs). Cross-sectoral technologies shall be applied in health management, and services such as telemedicine and personalized health management shall be developed. Retail pharmacies shall be supported in expanding professional services and health promotion functions to become health service stations better serving the public, thereby diversifying health-related consumer markets. The advantages of traditional Chinese medicine resources shall be harnessed to develop new consumption scenarios addressing anti-aging, elderly nursing care, rehabilitation and health management needs.

18. Enhancing the Pharmaceutical Industry's Social Value

The wider application of innovative drugs and medical devices for chronic diseases, infectious diseases, age-related diseases, rare diseases and other conditions shall be accelerated. The supply of health-protection products throughout the life cycle and health safeguards for priority population groups shall be strengthened. Intelligent health services shall be vigorously developed, and health protection and interventions for working populations shall be strengthened. Biosafety risk management and control capabilities shall be improved. Enterprises shall be guided in improving safety management systems and strengthening risk assessment, identification and early warning on a graded and classified basis. Development and application of advanced technologies and processes shall be supported to improve safety safeguards.

19. Cultivating the Pharmaceutical Industry's Cultural Value

The preservation and innovation of traditional Chinese medicine culture shall be promoted. The compilation and organization of ancient medical texts and development of classical prescriptions shall be strengthened, showcasing traditional Chinese medicine culture and achievements. Raw-material production bases and traditional Chinese medicine enterprises shall be encouraged to undertake science education and study activities integrating agriculture, culture and tourism. Modern pharmaceutical industrial culture shall be cultivated, authoritative science education resources developed, and public understanding of industrial and scientific innovation strengthened. Cultural soft power shall be enhanced, and pharmaceutical culture shall be integrated into national education. Traditional Chinese medicine culture and life-science education shall be provided in primary and secondary schools, artistic and literary works on pharmaceutical themes shall be supported, and China's pharmaceutical achievements and experiences shall be communicated effectively.

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(7) Improving Manufacturing and Supply Assurance and Strengthening the Foundations of Inclusive Health

20. Improving Diversified Assurance Systems

Monitoring of manufacturing and supply information for key drugs shall be strengthened, and systems ensuring the production and supply of priority medical and pharmaceutical materials shall be improved. Wider use of over-the-counter drugs for common and chronic diseases shall be promoted, with particular attention to securing medicines for children, older people, patients with rare diseases and other groups. The national pharmaceutical reserve management system shall be improved. The range, scale and structure of reserves shall be adjusted on a scientific basis, and production-capacity and technology reserves shall be fully utilized.

21. Strengthening the Supply of High-quality Essential Medicines and Medical Devices

The manufacturing quality excellence improvement initiative shall be implemented in depth. Pharmaceutical industrial enterprises shall be guided in participating in assessments of manufacturers' quality management capabilities and improving those capabilities. Quality improvement and life-cycle regulation of drugs and medical devices shall be strengthened. Enterprises shall be supported in implementing the relevant requirements of the newly revised Good Manufacturing Practice for Drugs (GMP), improving the overall quality of drugs in China. The performance and quality of devices such as diagnostic ultrasound systems, biochemical analyzers and electrocardiographs shall be continuously improved to meet basic medical service needs. The Essential Medicines List shall be dynamically optimized, prioritizing inclusion of clinically necessary, safe, effective and reasonably priced products.

22. Continuously Improving Access to Medicines

Cost-efficiency advantages across the entire industrial chain shall be fully harnessed to continuously improve coordinated supply capabilities for generic drugs, biosimilars, innovative drugs and medical devices. International supply-demand matching shall be strengthened, and priority products such as vaccines, diagnostic reagents and anti-infective drugs shall be supported in obtaining World Health Organization (WHO) prequalification and entering global procurement systems. International pharmaceutical supply cooperation shall be strengthened to improve rapid allocation and supply during epidemic outbreaks, major disasters and other emergencies. International pharmaceutical assistance shall be strengthened to support developing countries in improving disease prevention and control and medical treatment capabilities.

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Box 9. Improving Supply Assurance for Priority Medical and Pharmaceutical Materials

1. Ensuring the Manufacture and Supply of Medicines for Priority Population Groups

Development and application of drugs for rare diseases. For hemophilia, albinism, amyotrophic lateral sclerosis, phenylketonuria, mitochondrial diseases, multiple sclerosis, pulmonary alveolar proteinosis, Cushing's syndrome, Gaucher disease, Pompe disease, mucopolysaccharidoses and other rare diseases, every effort shall be made to advance frontier technologies such as cell therapy, gene therapy, oligonucleotide therapeutics, peptide drugs and somatostatin analogues, and to accelerate innovative research, development, translation and application of drugs for rare disease diagnosis and treatment.

Development of appropriate pediatric dosage forms and strengths. Taking account of children's physiological characteristics and ability to accept medicines, appropriate pediatric dosage forms, strengths and dedicated excipients shall be developed for oral, transdermal, nasal, inhalation and rectal preparations.

2. Reserve Management

Production-capacity reserves. In accordance with supply assurance needs, and taking into account the scale of physical reserves, product characteristics, production cycles and safety attributes, a list of manufacturers responsible for emergency supply under the national pharmaceutical reserve system shall be established, and production-capacity reserves shall be developed.

Technology reserves. A catalogue of strategic frontier technologies for national pharmaceutical reserves shall be established to address unknown disease risks, prevention and control of emerging and unexpected infectious diseases, and supply assurance during major emergencies. Pharmaceutical technology reserves shall be strengthened.

(8) Deepening International Industrial Cooperation and Establishing an Open and Mutually Beneficial Framework

23. Enhancing Industrial Competitiveness

Competitive strengths shall be developed more rapidly in chemical active pharmaceutical ingredients, advanced preparations, vaccines, antibody drugs, traditional Chinese medicines and medical devices. Cross-border pharmaceutical technology and service systems shall be improved, and professional capabilities in full-chain pharmaceutical research, development and manufacturing services (CRO/CDMO) for international markets shall be strengthened. Domestic enterprises shall be supported in participating actively in the global division of labor and cooperation in pharmaceutical innovation through joint research and development, joint commercialization and other arrangements. Intellectual property protection and utilization shall be strengthened to support innovative drugs and devices in entering international markets. International cooperation in drug regulation shall be strengthened, effective alignment between domestic and international regulatory rules and standards promoted, and regulatory coordination reinforced to improve the international recognition and influence of Chinese pharmaceutical products.

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24. Upgrading Industrial Cooperation

A cooperative pharmaceutical and health industry ecosystem shall be developed more rapidly. Cooperation with countries participating in the Belt and Road Initiative shall be strengthened, using international medical exchanges to promote the application of advanced Chinese diagnostic and treatment technologies, drugs and medical devices. Guidance on overseas development shall be strengthened. Industry associations, professional service providers and other entities shall be encouraged to expand overseas service networks covering research and development, registration, financing and manufacturing. Pharmaceutical industrial enterprises shall be supported in conducting international multicenter clinical trials and international registration of innovative drugs, and in expanding overseas research and development centers, manufacturing bases and sales networks.

25. Increasing Market Attractiveness

China's large domestic market shall be used to attract foreign pharmaceutical enterprises to expand their operations and investment in China and establish activities throughout the chain from product research and development and clinical translation to manufacturing. Policy advantages of pilot free trade zones, the Hainan Free Trade Port and the Guangdong-Hong Kong-Macao Greater Bay Area shall be harnessed to explore institutional innovations in cross-border data flows, cross-border regulatory cooperation and other areas, and establish efficient and convenient cross-border pharmaceutical service systems. The marketing of imported drugs and medical devices urgently needed in clinical practice shall be accelerated, and their manufacture in China shall be facilitated, driving the development of supporting industrial chains for high-end raw materials and excipients, equipment and consumables, and instruments and reagents. Localities with the necessary conditions shall be supported in accelerating the establishment of international innovation cooperation hubs and broadening and deepening international innovation cooperation.

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III. Strengthening Organization and Implementation

Relevant interministerial coordination mechanisms shall be used to coordinate strategic plans, major projects, major programs and supporting policies, and promote alignment among industrial, science and technology, regulatory, medical, healthcare security, financial and talent policies. Dynamic monitoring and evaluation of implementation shall be undertaken. Review and approval mechanisms shall be optimized, and a high-standard regulatory system shall be established and improved, commensurate with China's pharmaceutical research, development and manufacturing capabilities and aligned with advanced international standards. Artificial intelligence and other technologies shall be used to improve intelligent regulation.

Pricing, payment and use policies shall be improved; mechanisms for drug price formation throughout the life cycle shall be effectively implemented; and commercial health insurance shall be vigorously developed. Hospital adoption and use of innovative drugs and devices urgently needed in clinical practice shall be accelerated, and hospital-entry procedures and incentives optimized. Local initiatives connecting medical institutions with pharmaceutical industrial enterprises shall be supported, enabling more innovative drugs and devices to benefit patients promptly.

Public science communication on the pharmaceutical and health industry shall be strengthened. In-depth cooperation between industry organizations and relevant media shall be supported to jointly establish professional, diversified and multichannel public communication networks and improve pharmaceutical and health literacy. Talent support shall be strengthened, with increased recruitment of high-level, highly skilled, cutting-edge and urgently needed pharmaceutical professionals. National colleges, national practical training bases and colleges for outstanding engineers, and other institutions shall be used to strengthen interdisciplinary talent development. Industry organizations shall play their role in strengthening self-regulation and standardizing enterprises' manufacturing, operations and management, to achieve orderly competition, intensive development and greater brand influence.

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Source and Translation Notes

This English translation comprises the issuing notice and the complete 18-page Chinese Plan, including all 25 numbered priority tasks and Boxes 1-9. It is a translation prepared by Health Law Asia and is not an official English version issued by the Chinese authorities.

Official notice: Ministry of Commerce policy database, reproducing the Ministry of Industry and Information Technology notice, Gong Xin Bu Lian Gui [2026] No. 210, dated August 28, 2026.

https://policy.mofcom.gov.cn/claw/clawContent.shtml?id=106854

Official Chinese Plan attached to the notice:

https://picpolicy.mofcom.gov.cn/file/20260921/20260921111215965.pdf

The publication date of September 18, 2026 is corroborated by the MIIT's official explanatory publication. The notice itself does not specify a separate commencement date; the planning period is 2026-2030.

https://www.miit.gov.cn/jgsj/xfpgys/yy/art/2026/art_f18b30d0f5fd4635b6544c6d13097b98.html

Terminological note: In Box 2, the established term “induced pluripotent stem cells” is used for iPSC. In Box 4, “heat-shrinkable elastomers (TPE)” preserves the Chinese wording and abbreviation as printed; TPE conventionally denotes thermoplastic elastomers, whereas the Chinese expression printed in the source literally refers to heat-shrinkable elastomers.

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