The General Office of the State Council's Opinions on Deepening the Reform of Drug and Medical Device Regulation and Promoting the High-Quality Development of the Pharmaceutical Industry[1]

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OVERVIEW

This document, issued by the General Office of the State Council, delineates China's strategic framework for reforming its pharmaceutical and medical device regulatory systems, with the aim of promoting high-quality development and fostering innovation. By 2027, China intends to further strengthen its legal and regulatory infrastructure, enhance the efficiency of approval processes and elevate the quality standards of pharmaceutical products and medical devices. The reform agenda prioritizes several key areas, including the advancement of research and innovation, the enhancement of intellectual property protections, the support for Traditional Chinese Medicine (TCM) and the alignment of regulatory practices with international standards. These strategic reforms are designed to create a more efficient and attractive regulatory environment, thereby facilitating the expansion of foreign pharmaceutical enterprises within China's rapidly growing pharmaceutical and medical device markets.

Introduction

To the People's Governments of all Provinces, Autonomous Regions and Municipalities directly under the Central Government, as well as all Ministries, Commissions and directly affiliated Institutions of the State Council:

In order to thoroughly implement the indications and directives of General Secretary Xi Jinping on drug and medical device regulation, as well as the development of the pharmaceutical industry, and to comprehensively deepen the reform of drug and medical device regulation while ensuring the high-quality development of the pharmaceutical industry, the following opinions are hereby put forward with the approval of the State Council.

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

1. General requirements

Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, PRC aims to fully implement the principles of the 20th National Congress of the Communist Party of China, as well as the Second and Third Plenary Sessions of the 20th Central Committee. Adhering to a regulatory development path that is scientific, law-based, internationalized and modernized; PRC aims to coordinate high-quality development with high-level security, deepen comprehensive reforms in the regulation of drugs and medical devices, accelerate the establishment of a unified national market in this sector and create a globally competitive innovation ecosystem. This process will drive China's transition from a major pharmaceutical country to a pharmaceutical powerhouse, better meeting the people's demand for high-quality drugs and medical devices.

By 2027, the legal and regulatory framework for drug and medical device supervision will be further improved. The regulatory system, mechanisms and approaches will be better aligned with the needs of pharmaceutical innovation and high-quality industrial development. The quality and efficiency of the review and approval process for innovative drugs and medical devices will be significantly enhanced, whole-life-cycle supervision will be notably strengthened and overall quality and safety standards will be comprehensively elevated. A regulatory system that aligns with pharmaceutical innovation and industrial development will be established. By 2035, the quality, safety, efficacy and accessibility of drugs and medical devices will be fully ensured. The pharmaceutical industry will have stronger innovation capabilities and global competitiveness, with regulatory modernization basically achieved.

2. Increase support for the research and innovation of pharmaceuticals and medical devices

(1) Improve the review and approval mechanism to fully support major innovations: According to the requirements of "one enterprise one policy ", it’s necessary allocating more review and approval resources to key innovative drugs and medical devices that are urgently needed in clinical settings. Strengthen communication and provide personalized guidance throughout the entire process, including clinical trials, registration applications, inspections and reviews. (Led by the National Medical Products Administration)

(2) Increase support for the research and innovation of traditional Chinese medicine (TCM): Improve the review evidence system that combines TCM theories, human experience and

clinical trials. Establish a mechanism for medical institutions to systematically collect and organize human experience data. Enhance the regulatory system suitable for TCM characteristics. Actively support the transformation of prescriptions from renowned TCM practitioners and medical institutions into innovative TCM products. Encourage the use of new technologies, processes and formulations to improve already marketed TCM products. (Led by the National Medical Products Administration, with responsibilities shared by the Ministry of Industry and Information Technology, National Health Commission, and National Administration of Traditional Chinese Medicine)

(3) Leverage standards to lead innovation in drugs and medical devices: Deepen the implementation of the national action plan to enhance standards for drugs and medical devices, actively advancing standard research and transformation for new technologies, methods and tools. Improve the national drug standard database and publish timely updates to the online version of the Chinese Pharmacopoeia. Optimize the medical device standard system and research the establishment of standardization technical organizations for cutting-edge medical devices like artificial intelligence and medical robots. Strengthen the standards for TCM medical devices. (Led by the National Medical Products Administration, with responsibilities shared by the Ministry of Industry and Information Technology, National Health Commission, State Administration for Market Regulation and National Administration of Traditional Chinese Medicine)

(4) Improve the relevant systems for intellectual property protection of drugs and medical devices: For some drugs approved for market entry, provide a certain data protection period for trial data and other data submitted by applicants that are self- obtained and not disclosed. Grant a certain market exclusivity period for eligible rare disease drugs, pediatric drugs, the first chemical generics and exclusive TCM products. Accelerate the patent layout for original achievements in drugs and medical devices, enhancing patent quality and the effectiveness of conversions. (Responsibilities shared by the National Intellectual Property Administration and the National Medical Products Administration)

(5) Actively support the promotion and use of innovative drugs and medical devices: Increase the clinical comprehensive evaluation of innovative drugs and strengthen the analysis and application of evaluation results. Research and trial a self-evaluation system for newly marketed drugs based on pharmaceutical and clinical value, optimizing the online services for newly launched drugs. Uphold the basic medical insurance's basic

coverage functionality, improve the mechanism for adjusting the medical insurance drug list, study and regulate the medical consumables list and medical service item list, incorporate eligible innovative drugs and medical devices into the medical insurance payment scope according to procedures. Encouraging medical institutions to procure and use them and improve the multi-tiered medical security system to enhance the diverse payment capabilities for innovative drugs. Actively disseminate accurate and comprehensive information about innovative drugs and medical devices to the public. (Responsibilities shared by the Ministry of Industry and Information Technology, National Health Commission, State Administration for Market Regulation, National Medical Insurance Administration, and National Medical Products Administration)

3. Improve the quality and efficiency of drug and medical device review and approval

(6) Strengthen pre-registration guidance for drugs and medical devices: Reduce the waiting time for communication regarding clinical trials of urgently needed innovative drugs. Implement multi-channel and multi-tiered communication strategies, including the Drug Review Cloud Classroom and Device Review Cloud Classroom. Enhance the role of review inspection sub-centers and the collaborative mechanism between central and local authorities for medical device innovation. Strengthen the promotion and interpretation of registration and application rules. (led by the National Medical Products Administration)

(7) Accelerate the approval and market entry of clinically needed drugs and medical devices: Prioritize the review and approval of applications for clinically needed products, including: cell and gene therapy drugs, drugs that have already been launched overseas, combination vaccines, radioactive drugs, substitute products for rare and endangered medicinal materials, high-end medical equipment such as medical robots, brain-computer interface devices, radiation therapy equipment, medical imaging devices and innovative traditional Chinese medicine diagnostic and treatment devices. (Led by the National Health Commission and the National Medical Products Administration, according to their respective duties)

(8) Optimize the clinical trial review and approval mechanism: Provincial-level drug regulatory departments submit applications, after approval by the National Medical Products Administration (NMPA), pilot projects for optimizing the clinical trial review and approval of innovative drugs will be launched in certain regions, shortening the review and approval timeline from 60 working days to 30 working days. The review and approval

timeline for medical device clinical trials will also be shortened from 60 working days to 30 working days. Optimize the filing mechanism for bioequivalence tests. (Led by the NMPA, with cooperation from provincial-level people's governments in pilot regions)

(9) Optimize the review and approval of supplementary drug applications: Provincial- level drug regulatory departments submit applications, after approval by the National Medical Products Administration (NMPA) and pilot projects for optimizing the review and approval process of supplementary drug applications will be launched in certain regions. The review timeline for supplementary applications that require inspection and testing will be shortened from 200 working days to 60 working days. The management of active pharmaceutical ingredients will be optimized and the entity responsible for API registration can be legally changed. (Led by NMPA, with cooperation from provincial-level governments in pilot regions)

(10) Optimize the registration inspection of drugs and medical devices: The registration inspection for drugs, biological product batch release inspection and import drug customs inspection will reduce the required amount per batch from three times the full inspection quantity to twice. A green channel for priority inspection of innovative drugs and medical devices will be established. Clinical urgently needed drugs and medical devices will be inspected immediately upon receipt. (Led by NMPA)

(11) Accelerate the review and approval of drugs and medical devices for rare diseases: For qualifying innovative drugs and medical devices for rare diseases, clinical trials will be waived. The batch inspection requirement for registration of drugs for rare diseases will be reduced from three batches to one batch and the amount per batch will be reduced from three times the full inspection quantity to twice the quantity. Based on product risks, the import review and post-marketing inspection for rare disease drugs will be coordinated to shorten the waiting time for overseas verification. Exploration will be conducted to allow specific medical institutions to import urgently needed rare disease drugs and medical devices that are not registered or marketed domestically. National medical centers will be encouraged to increase the allocation and use of drugs and medical devices for rare diseases. High-level medical institutions will be encouraged to independently develop diagnostic reagents for rare diseases that have not yet been marketed in China. (Led by National Health Commission and NMPA)

4. Enhance Compliance in the Pharmaceutical Industry through Efficient and Strict Regulation

(12) Promote the authorization of batch release for biological products (Vaccines): Based on a thorough risk assessment, gradually expand the authorization for the batch release of biological products (vaccines) to include provincial-level drug regulatory department inspection and testing agencies and product categories. The batch release timeline for seasonal influenza vaccines and other products will be shortened to within 45 working days. (Led by NMPA, with cooperation from relevant provincial-level governments in pilot regions)

(13) Promote the improvement of generic drug quality: Optimize the review and inspection mechanisms for generic drugs and increase the intensity of dynamic inspections before approval based on product risks. Strengthen supervision of commissioned research and development, contract manufacturing, supporting enterprises with high levels of informatization, quality assurance and risk prevention capabilities. Gradually extend the consistency evaluation of quality and efficacy for generic drugs to dosage forms such as eye drops, patches and sprays. (Led by NMPA)

(14) Promote the informatization of pharmaceutical and medical device production and inspection processes: Promote the integration of new-generation information technology with the pharmaceutical industry chain and support the digital transformation of pharmaceutical and medical device manufacturing enterprises. Strictly supervise vaccine manufacturers to fully implement informatization requirements for production and inspection processes. Gradually advance the informatization transformation of blood products manufacturing and promote the establishment of an informatized management system for blood products covering the entire process from plasma collection to production and inspection. (Led by Ministry of Industry and Information Technology, National Health Commission and NMPA)

(15) Improve the efficiency of pharmaceutical and medical device supervision and inspection: Strengthen quality and safety warning education for enterprises and urge them to improve their quality management systems comprehensively. Determine inspection frequencies based on the enterprise and product risk levels and reduce redundant inspections. Encourage national and provincial-level drug regulatory departments to collaborate on site inspections for production enterprises, including registration and

production quality management standard compliance inspections. For enterprises producing both Class I and Class II or III medical devices, combined inspections will be conducted. (Led: NMPA)

(16) Strengthen the vigilance for innovative drugs and medical devices: Guide the holders of marketing authorizations for innovative drugs to establish a complete pharmacovigilance system, actively monitor, report, analyze adverse reactions and continue post-market studies. Based on the risk characteristics of innovative drugs and medical devices, improve adverse drug reaction and medical device adverse event monitoring platforms. Strengthen proactive monitoring of innovative drugs and medical devices after-market release. (Led by National Health Commission, NMPA according to their responsibilities)

(17) Enhance supervision and effectiveness of new pharmaceutical distribution models: Establish a safety risk-sharing alliance for the online sale of pharmaceuticals and medical devices and hold third-party platforms responsible. Support wholesale enterprises in effectively integrating warehousing and transportation resources to build a multi-warehouse collaborative logistics management model. Optimize the licensing process and improve the retail chain rate. Traditional Chinese medicine (TCM) decoction pieces processed according to provincial standards may be sold across provinces and TCM formula granules produced according to national pharmaceutical standards can be sold directly across provinces. (Led by NMPA, with cooperation from the Ministry of Commerce, National Health Commission, State Administration for Market Regulation, National Administration of Traditional Chinese Medicine)

5. Support the expansion of foreign cooperation and openness in the pharmaceutical industry

(18) Deepen the implementation of international harmonized regulatory rules: Continue to promote alignment of pharmaceutical review technical requirements with the rules of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human use, support drug clinical trial institutions in participating in early-stage clinical development of innovative drugs and support international multi-center clinical trials. Promote the simultaneous development, submission, review and marketing of global drugs in China. Actively promote the implementation of technical guidelines from international medical device regulatory forums and the Global Harmonization Task Force (GHTF) in China. (Led by National Health Commission and NMPA)

(19) Explore a segmented production model for biological products : Provincial-level drug regulatory departments submit applications, and after approval by NMPA, pilot projects for segmented production of biological products with special process or equipment requirements will be launched in certain regions. Segmented production model for biological products starts with antibody-drug conjugates, multivalent vaccines and other segmented productions. Support qualified overseas drug marketing authorization holders to conduct cross-border segmented production under a unified pharmaceutical quality management system, either through self-built capacity or contract manufacturing. (Led by NMPA, with cooperation from provincial- level governments in pilot regions)

(20) Optimize the approval process for imported pharmaceuticals and medical devices: Simplify the review and approval of traditional Chinese patent medicines already marketed in Hong Kong and Macau. Optimize the management of imported medicinal materials and expand the import of high-quality foreign medicinal materials. Allow imported drugs already marketed overseas to be sold in China after obtaining Chinese pharmaceutical approval documents for batches of commercially scaled products that meet the requirements. Optimize the review and approval process for the transfer of imported pharmaceutical and medical device products already marketed in China to domestic production and support foreign-invested enterprises in bringing original drugs and high-end medical equipment for domestic production. (Led by NMPA)

(21) Support pharmaceutical and medical device export trade**:** Accelerate participation in the International Pharmaceutical Inspection Cooperation Scheme. Expand the scope of enterprises eligible to issue export certificates to all qualified enterprises producing pharmaceutical and medical devices according to production quality management standards. Strengthen international exchanges and cooperation on Chinese medicine resources, actively promote international regulatory policy dissemination and exchanges and support the registration and marketing of clinically advantageous Chinese medicines overseas. (Led by Ministry of Commerce, National Administration of Traditional Chinese Medicine and NMPA)

6. Build a regulatory system adapted to the development and safety needs of the industry

(22) Continuously strengthen regulatory capacity building: Optimize the setup of regulatory technical support institutions, strengthen the construction of specialized teams and enhance the quality of technical personnel. Gradually assign more responsibilities to evaluation and inspection sub-centers that meet capacity standards, expand the scope of evaluation products and the inspection of enterprises, and steadily develop evaluation-inspection capabilities adapted to regional industry characteristics. Promote the evaluation capability and personnel capacity evaluation of provincial-level medical device regulatory departments. Encourage local governments to improve local regulatory systems and mechanisms, strengthen team capacity and actively promote pilot reforms for evaluation and other work. (Led by NMPA, with cooperation from the Ministry of Human Resources and Social Security)

(23) Develop pharmaceutical regulatory science: Lead by the National Key Laboratory of Pharmaceutical Regulatory Science, strengthen the construction of innovative research bases for pharmaceutical regulatory science. Deploy pharmaceutical regulatory science and technology research tasks, improve the transformation of research results and accelerate the development of new tools, standards and methods to support regulatory decision-making. (Led by Ministry of Science and Technology and NMPA)

(24) Strengthen regulatory informatization: Promote the online managing of all government service items for pharmaceutical and medical device regulation, from application, acceptance, review to certification. Improve the National Pharmaceutical Smart Regulatory Platform, strengthen the aggregation and governance of product archives and credit files in order to explore a more penetrative supervision. Promote the implementation of unique medical device identification in supporting the development and governance of medical, insurance and pharmaceutical coordination. Strengthening the construction of a full-chain pharmaceutical traceability system, implementing corporation, gradually achieve traceability throughout the production, distribution and use process. (Led by NMPA, with cooperation from the National Development and Reform Commission, Ministry of Industry and Information Technology, National Health Commission, and National Medical Insurance Administration)

Conclusion:

All regions and relevant departments should integrate and strengthen the leadership of the Party in the entire process of deepening pharmaceutical and medical device regulatory reform, recognize the importance of using reform to promote high-quality development in the pharmaceutical industry and implement the requirements of the "four strictest" in the implementation of this document. Relevant departments should enhance cooperation, gather efforts, ensure funding and talent support and ensure the implementation and effectiveness of these policies. Major matters should be reported to the Central Committee and the State Council in a timely manner.

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