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

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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. 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