Materials related to new medical therapies

INTRODUCTION:

Relevant definition: New therapies refer to treatment methods that, in contrast to traditional surgical, radiotherapy, chemotherapy, and conventional drug treatments, employ new technical principles, mechanisms of action, administration methods, or treatment approaches. Its scope covers multiple fields such as medicine, medical equipment, and rehabilitation. Among them, the new medical therapies are the most core and the most actively researched branch. They mainly intervene in the disease process through new drug molecules, biological agents or treatment technologies, covering cell and gene therapy, precision targeted drugs, innovative drugs, new radiological drugs, biological products, etc. The industries involved include innovative drugs, improved new drugs, characteristic raw materials, high-end medical devices and pharmaceutical excipients, etc.

On June 10, 2025, the Center for Drug Evaluation of the National Medical Products Administration solicited public opinions on the "Scope, Classification and Interpretation of Advanced Therapeutic Drugs (Draft for Comment)". According to this draft for comment, drugs such as cell therapy drugs and gene therapy drugs that are produced through in vitro operations and exert their expected functions in the human body Drugs produced by innovative technologies (methods) based on microorganisms, cells, genes or tissue engineering all fall within the category of advanced therapeutic drugs, which are also closely related to new medical therapies.

QUESTION 1: Are there any current national policies or welfare subsidies promoting the development of new medical therapies?

1. At the national level: On June 30, 2025, the National Healthcare Security Administration and the National Health Commission jointly issued the "Several Measures to Support the High-Quality Development of Innovative Drugs", proposing

16 specific measures in 5 aspects. First, increase support for the research and development of innovative drugs. By enhancing information sharing among medical care, medical insurance, and pharmaceuticals, and under the premise of ensuring data security and compliance, utilize medical insurance data to provide services for the research and development of innovative drugs and help determine the research and development direction. At the same time, commercial insurance is encouraged to provide long-term investment in the form of investment funds, and the communication mechanism between the medical insurance department and enterprises is optimized. Policy guidance on drug list access will be given, and relevant major science and technology projects will be organized and implemented to promote the research and development of innovative drugs in key areas. Second, support innovative drugs in being included in the basic medical insurance drug list and the commercial health insurance innovative drug list. Improve the dynamic adjustment mechanism of the medical insurance list, and include innovative drugs that meet the conditions in accordance with the procedures. In special circumstances, temporary inclusion paths can be studied. Reasonably determine the medical insurance payment standards, add a commercial insurance list of innovative drugs, include high-value innovative drugs, and strengthen real-world research on innovative drugs, promoting the connection between research results and list access, etc. Third, support the clinical application of innovative drugs, optimize the procedures for drug listing, and enable innovative drugs included in the medical insurance and commercial insurance directories to be directly listed, thereby enhancing service efficiency. Promote the rapid entry of innovative drugs into designated medical institutions. Medical institutions should adjust their allocation within three months after the update of the list, and they are not subject to the "one product, two regulations" restrictions. Strengthen the capacity building of medical institutions to use innovative drugs, improve the management of medical insurance payment, establish a "case-by-case discussion" mechanism, and at the same time, do a good job in the "dual-channel" management and the construction of the "medical insurance drug cloud platform" to ensure the supply and settlement of drugs. Fourth, enhance the diversified payment

capacity for innovative drugs, give full play to the functions of the multi-level medical security system, encourage commercial insurance and medical mutual aid to include innovative drugs, promote charitable donations to support the medication of disadvantaged groups, and the medical insurance department should provide cooperation support such as data sharing for relevant commercial insurance. At the same time, by leveraging our country's advantages, we will build an innovative drug trading platform to promote the development of the global market for innovative drugs and facilitate two-way exchanges. Fifth, strengthen organizational guarantees, enhance coordination and cooperation between medical insurance and health and wellness departments, implement management responsibilities, and form a synergy. Strengthen the assessment of the implementation effect of policies and ensure the smooth connection and coordination of policies. Actively promote and create a favorable atmosphere, strengthen the supervision of medical insurance funds, incorporate the payment of innovative drugs into the key scope of supervision, and implement the application of drug traceability codes for supervision.

2. Provincial and municipal levels: On August 12, 2025, the Jiangsu Provincial Government issued the "Several Policy Measures for Comprehensively Promoting In-depth Reform of Drug and Medical Device Supervision and Promoting High-Quality Development of the Pharmaceutical Industry". Six aspects and 23 specific measures have been proposed, including promoting the pilot implementation of key reforms, continuously optimizing review and approval services, facilitating innovation in medical research and development, supporting the inheritance and innovative development of traditional Chinese medicine, expanding high-level opening up to the outside world, and enhancing the capacity and level of modern supervision. For instance, in terms of review and approval services, it is proposed to optimize the management of medical device registration and licensing as well as post-marketing changes of drugs. The efficiency of medical device registration and drug change management will be enhanced through measures such as simplifying procedures, parallel approval, and shortening time limits. Moreover, the reform of integrated drug circulation will be advanced, and the sharing of warehousing

resources will be supported. At the same time, we should enhance pre-service guidance and communication, establish communication mechanisms and training platforms, and provide enterprises with full-process policy and technical support as well as precise services. In terms of supporting the research and development of innovative products, it is proposed to strongly support technological breakthroughs and the research and development of innovative products in cutting-edge fields such as cell and gene therapy through the deployment of science and technology plans and the "direct access without application" reward policy. At the same time, we should promote the efficient transformation of scientific research achievements, strengthen the construction of clinical research capabilities to shorten the trial cycle and promote mutual recognition of ethics, support the promotion and application of innovative products, and set up a green channel for innovative products to be listed online to accelerate their market application. In addition, measures such as increasing medical insurance payment support and incorporating innovative drugs into the "dual-channel" management have been taken to comprehensively promote research and development innovation and the transformation of achievements in the pharmaceutical industry.

Explanation of the "Direct Access without Application" reward policy. On March 1, 2024, the Provincial Department of Industry and Information Technology and the Provincial Department of Finance will take the lead in working with the Provincial Drug Administration, the Provincial Health Commission, the Provincial Medical Insurance Bureau and other departments to study and formulate the implementation plan for the reward policy for innovative drugs and medical devices. In accordance with the policy measures supporting the innovative development of the biopharmaceutical industry as stipulated in the "Several Policy Measures for Promoting the Sustained Recovery and Improvement of the Economy" (Su Fa [2023] No. 9) issued by the provincial committee of the Communist Party of China and the provincial government, we will strengthen the support for enterprise development through the "no application required, direct and fast access" approach. The reward recipients are enterprises within the province that were approved for innovative drugs, improved new drugs, and Class III innovative medical devices in the previous year.

The policy reward standards are for innovative drugs and medical devices produced within the province. In accordance with the standards clearly stipulated in the "Notice of the Provincial Government on Issuing Several Policy Measures to Promote the High-Quality Development of the Province's Biomedical Industry" (Su Zheng Fa [2021] No. 59), the provincial finance will provide support for each innovative drug, improved new drug, and Class III innovative medical device. Rewards of 10 million yuan, 3.3 million yuan and 6.6 million yuan will be given respectively. For innovative drugs and medical devices produced by entrusting other provinces, financial support will be allocated at 70% of the reward standard for production within the province.

Other provinces and cities, such as Hainan and Guangdong, have also successively introduced a number of measures, mainly focusing on areas such as financial rewards, research and development support, approval optimization, industrial collaboration, and improvement of payment systems.

3. Zhenjiang Economic Development Zone: On April 29, 2025, the "Several Measures of Zhenjiang Economic Development Zone to Support the High-Quality Development of the Biomedical and Health Industry" was issued, which proposed six major measures: First, encourage the agglomeration development of industries; second, support the research and innovation of drugs; third, strengthen the development of high-end medical devices; fourth, support the entrepreneurship of talent teams; fifth, support the construction of production sites.

QUESTION 2: What are the current requirements of the state for new therapies to enter clinical trials? What conditions must be met to be finally approved and officially enter the market?

At present, there is no specific law or regulation that makes specific requirements for the clinical trials of new therapies. According to the specific circumstances of new therapies, the relevant regulations on clinical trials of drugs, medical devices, etc. shall be applied respectively. The National Medical Products Administration is in charge of the national registration and filing management of drugs and medical devices.

In terms of pharmaceuticals: According to the "Pharmaceutical Administration Law of the People's Republic of China" and the "Measures for the Administration of Drug Registration", there are several processes for a new drug from research and development to entering the market.

Phase One: Preclinical research. Drug registration applicants conduct pharmaceutical and pharmacological toxicological research during the basic stage of drug development. This stage has not yet been tested on humans.

Phase Two: Clinical Trial Application. After completing sufficient preclinical research, the drug registration applicant submits a clinical trial application to the Center for Drug Evaluation of the National Medical Products Administration.

Phase Three: Clinical Trials. Drug registration applicants conduct drug research on humans for the purpose of drug marketing registration to determine the safety and efficacy of the drug. Drug clinical trials are classified into Phase I clinical trials, Phase II clinical trials, Phase III clinical trials, Phase IV clinical trials, and bioequivalence trials. According to the characteristics of the drug and the research purpose, the research content includes clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing studies.

Phase Four: Application for marketing authorization of the drug. After the drug registration applicant has completed the research on pharmacy, pharmacology and toxicology, and drug clinical trials that support the drug's marketing registration, determined the quality standards, completed the verification of commercial-scale production processes, and is ready to accept the drug registration verification and inspection, it shall submit an application for drug marketing authorization to the Center for Drug Evaluation of the National Medical Products Administration and submit the relevant research materials as required by the application materials.

Phase Five: Technical Review and Verification. The Center for Drug Evaluation of the National Medical Products Administration shall organize pharmaceutical, medical and other technical personnel to review the applications for marketing authorization of drugs that have been accepted as required. During the review process, if the drug registration verification and testing are initiated based on risks, the relevant technical

institutions shall complete the verification and testing work within the prescribed time limit. The Center for Drug Evaluation conducts a comprehensive review of the safety, efficacy and quality controllability of drugs based on the drug registration application materials, verification results, test results, etc. Over-the-counter drugs should also be transferred to the Center for Drug Evaluation for the suitability review of over-the-counter drugs.

Phase 6: Approval Decision and Listing. If the comprehensive review conclusion is passed, the National Medical Products Administration will approve the drug for marketing and issue a drug registration certificate. After a drug is approved for marketing, the holder shall produce the drug in accordance with the approved production process and quality standards, and refine and implement them in accordance with the requirements of the Good Manufacturing Practice for Drugs.

At the same time, for new drugs that meet the conditions, the accelerated registration process for drug marketing can be initiated: ① For drug clinical trials included in the breakthrough therapy drug program, the following policy support will be provided: (1) Applicants can submit communication and exchange applications to the National Center for Drug Evaluation at key stages of drug clinical trials, and the center will arrange for review personnel to conduct communication and exchange. (2) The applicant may submit the interim research materials to the National Center for Drug Evaluation. Based on the existing research materials, the Center for Drug Evaluation will offer opinions or suggestions on the next research plan and feed them back to the applicant. ② For drugs with obvious clinical value that are urgently needed in clinical practice, such as those in short supply, innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases, vaccines and innovative vaccines urgently needed for disease prevention and control, drugs included in the breakthrough therapy drug program, and drugs that meet the conditional approval requirements, applications can be made for the priority review and approval procedure. The National Center for Drug Evaluation provides the following policy support to drug marketing authorization applications that are included in the priority review and approval procedure: (1) The review period for

drug marketing authorization applications is 130 days; (2) For rare disease drugs that are urgently needed in clinical practice and have been marketed overseas but not in China, the review period is 70 days. (3) Where verification, inspection and approval of the generic name of a drug are required, priority shall be given to such arrangements. (4) After communication and confirmation, technical materials can be supplemented and submitted.

2. Regarding medical devices: According to the "Regulations on the Supervision and Administration of Medical Devices" and the "Measures for the Administration of Medical Device Registration and Filing", China implements classified management of medical devices based on their risk levels. The first category is subject to filing management, while the second and third categories of medical devices need to be registered. The Medical Device Technical Review Center is responsible for the technical review of clinical trial applications for medical devices that require clinical trial approval, as well as related registration, change and other applications. From R&D to market entry, there are several processes as follows: The first stage: Product finalization and classification; Phase Two: Product inspection and clinical Evaluation. Most Class II medical devices and some Class III medical devices that meet the exemption conditions do not require clinical trials. For those that need to undergo clinical trials, the process of submitting an application, obtaining approval, conducting clinical trials, and issuing clinical trial reports shall be followed. Phase Three: Submit the registration application; Phase Four: Approval and Issuance of certificates Phase Five: Post-listing supervision.

The National Medical Products Administration gives priority to the approval of urgently needed medical devices in clinical practice and implements special approval for innovative medical devices, encouraging research and innovation in medical devices and promoting the high-quality development of the medical device industry. The state has issued the corresponding "Detailed Rules for the Review of Applications for Priority Approval of Medical Devices by Medical Device Technology Review Centers" and "Detailed Rules for the Review of Applications for Special Review of Innovative Medical Devices by Medical Device Technology

Review Centers".

QUESTION 3: If a new drug has a high therapeutic effect, a wide range of applications but is relatively expensive, what measures will the state generally take?

The first is to increase support for medical insurance payments. According to the fund's capacity to bear, the negotiated drugs in the national medical insurance drug list will be included in the "dual-channel" management in accordance with the procedures. Support cases that meet the conditions for using innovative drugs and medical devices to be included in the special case for individual discussion. Promote the application of medical insurance data empowerment and facilitate the realization of rapid claims settlement for inclusive commercial medical insurance. The funds in the personal accounts of employee medical insurance can be used to purchase eligible universal commercial medical insurance products for close relatives.

The second is to give full play to the functions of the multi-level medical security system. Encourage commercial health insurance and medical mutual aid to include innovative drugs in their coverage, and promote enterprises and individuals to support the use of innovative drugs by people in difficulty through charitable donations and other means. The medical insurance department will provide cooperative support in terms of data sharing and settlement for eligible commercial health insurances. The application cases of innovative drugs within the coverage of relevant commercial health insurances may not be included in the payment by disease type and will be paid after going through the review and evaluation procedures.

QUESTION 4: Do the national and local governments currently have any relevant policies to encourage entrepreneurs in the pharmaceutical industry, and through what methods? What conditions can the government offer to entrepreneurs during the process of starting a business?

1. At the national level: This will be carried out from the perspectives of opening up medical insurance data to support research and development, establishing a dynamic

adjustment mechanism for the medical insurance directory, providing policy preferences for the inclusion of innovative drugs in medical insurance, and improving the negotiation and renewal rules for the development of innovative drugs. The policy incentives for industry entrepreneurs are mainly formulated by each local area in light of their actual conditions.

2. At the local government level: Surrounding regions such as Suzhou Industrial Park have issued the "Implementation Measures for Accelerating the High-Quality Development of the Biomedical and Health Industry" this year, focusing on key areas such as innovative drugs, high-end medical devices, and health. It will be carried out from eight aspects: the large-scale development of enterprises, the implementation of high-quality incremental projects, the listing and application promotion of innovative products, equity financing, credit support, artificial intelligence empowerment, and the innovation of institutional mechanisms.

In 2025, Taizhou issued the "Several Policy Measures for Promoting the Construction of a Strong City in Industrial Science and Technology Innovation", clearly stating that it will introduce, cultivate and make good use of all kinds of science and technology innovation talents. It will focus on talent introduction and cultivation through forms such as providing financial rewards, talent introduction subsidies, holding science and technology innovation training courses for entrepreneurs, and distributing living subsidies, to optimize the ecosystem of science and technology innovation talents.

3. Zhenjiang Economic Development Zone: It has issued the "Several Measures to Support the High-Quality Development of the Biomedical and Health Industry", providing the following support policies for relevant entrepreneurs

The first is to support talent teams in starting businesses. Support will be provided to eligible talents in areas such as housing, medical care and children's education. Further deepen the "competition and evaluation system", and provide certain financial subsidies to the organizers of industrial innovation and entrepreneurship competitions.The implementation of high-quality projects direct recognition mechanism, innovative talents and high-quality entrepreneurial projects hired by enterprises with high salaries, directly identified as the district "Chuan Shan" special

key funding. For talent teams in the biomedicine and big health fields that receive talent project funding, individual funding and team funding can be enjoyed cumulatively.

The second is to support the construction of production sites. Accelerate the improvement of infrastructure support for the biomedicine and big health industry, and strengthen the public service platform for industrial technology research and development. For enterprises that build or renovate GMP factories and obtain drug production licenses or medical device production licenses, a maximum of 30% of the actual cost of building or renovating GMP factories, at a unit price of 2,000 yuan per square meter, will be provided with financial support of up to 10 million yuan.

The third is to strengthen on-site assistance services. Strengthen the forward-looking guidance of registration review, and give priority to conducting registration sampling and GMP compliance checks for key research and development drugs. For key innovative drugs, improved new drugs and Class III medical devices under research and development, we provide services such as pre-review of application materials and priority arrangement of registration testing. Encourage medical institutions to give priority to the allocation and use of corresponding innovative drugs and medical devices based on clinical needs and hospital characteristics.

QUESTION 5: As a regulatory authority, what drug regulatory measures will be taken for new therapies after they enter the market?

1. Supervision in the production process: According to the functional boundaries of the market supervision departments at the provincial, municipal, county and district levels, the provincial drug Administration is responsible for the licensing, inspection and punishment of drug production. It will be specifically implemented by the Zhenjiang Inspection Branch of the Jiangsu Provincial Drug Administration.

2. Supervision in the operation and use links: The provincial drug administration is responsible for the wholesale licensing of drugs, the licensing of retail headquarters, the filing of third-party platforms for online sales, as well as inspection and punishment. The county-level market supervision and administration departments are

responsible for the inspection and punishment of drug retail and medical device operation licenses, as well as the quality inspection and punishment in the use links of drugs and medical devices.

According to the functions, the following regulatory measures are in place: First, issue drug business licenses prudently and determine in accordance with the law whether the conditions for engaging in drug business activities are met. Second, we will strengthen the supervision of key varieties. For blood products, cell therapy biological products, etc., we will focus on inspecting the purchase and sales channels, qualification reviews, storage and preservation conditions, etc. We will severely punish illegal acts such as purchasing drugs from illegal channels, selling prescription drugs without prescriptions, operating and using expired medical devices, and transporting and storing them in violation of the requirements indicated on the instructions and labels. Third, penalties will be imposed more severely in accordance with the special circumstances stipulated in the Drug Administration Law. For the acts of passing off anesthetic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, and precursor chemicals for drug manufacture as other drugs, or passing off other drugs as the above-mentioned drugs, and producing and selling counterfeit and substandard drugs mainly for pregnant women and children.

QUESTION 6: What are the current policy restrictions regarding the use of live bacteria for human treatment?

Live bacteria belong to biological products. Biological products refer to drugs prepared from biological materials such as microorganisms, cells, and various animal and human tissues and liquids obtained by common or through biotechnologies such as genetic engineering, cell engineering, protein engineering, and fermentation engineering, which are used for the prevention, treatment, and diagnosis of human diseases.

The market supervision department is mainly responsible for the quality and safety supervision of biological products. For the supervision of biological products, the relevant provisions of the "Pharmaceutical Administration Law of the People's

Republic of China" mainly apply. The term "drugs" as used in the "Pharmaceutical Administration Law" includes traditional Chinese medicine, chemical drugs and biological products, etc. Biological products are managed as drugs. Their research and development registration, marketing authorization, operation and use, as well as supervision and management are all the same as those of ordinary drugs.

The use of live bacteria for human treatment is a specific medical practice, and its policy restrictions are approved by the national and local health administrative departments.