Announcement of the Center for Medical Device Evaluation of the National Medical Products Administration on Matters Concerning Further Enhancing Support for Innovative Medical Devices[1]

Authority: **State Drug Supervision and Administration Bureau (replaced)**

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In order to implement the *Opinions of the General Office of the State Council on Deepening the Reform of Drug and Medical Device Regulation to Promote the High-Quality Development of the Pharmaceutical Industry* (Guo Ban Fa [2024] No. 53), thoroughly carry out General Secretary Xi Jinping's important instructions on the regulation of drugs and medical devices and the development of the pharmaceutical industry, promote the high-quality development of the medical device industry, enhance support for R&D and innovation in medical devices, and direct evaluation and approval resources toward key innovative medical devices urgently needed in clinical settings, the Center for Medical Device Evaluation (hereinafter referred to as the "CMDE") of the National Medical Products Administration (NMPA) has decided, from the date of this notice, to further strengthen guidance services for the R&D of innovative medical devices in accordance with the principles of "early involvement, tailored strategies for each enterprise, full-process guidance, and coordinated review." The relevant matters are hereby announced as follows:

I. Pre-Review of Clinical Trial Protocols for Innovative Medical Devices

For innovative medical device products, after the applicant completes preclinical R&D and, where necessary, feasibility clinical studies, the applicant may submit a request for pre-review of the clinical trial protocol via the major technical issue consultation pathway opened by the CMDE for innovative products. The applicant must submit the proposed clinical trial protocol, a summary of the rationale for the study, relevant supporting materials, and necessary preclinical research data. The CMDE will, based on the applicant's request, conduct a pre-review

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of the clinical trial protocol, and the resulting opinions will serve as an important reference for subsequent technical evaluations.

II. Clinical Evaluation for Non-Innovative Medical Devices

For non-innovative medical device products, applicants must carry out clinical evaluations in accordance with relevant laws and regulations. Applicants are encouraged to fully consult the technical guidance documents issued by the CMDE, including: technical Guidelines for Clinical Evaluation of Medical Devices, technical Guidelines for Clinical Trials of In Vitro Diagnostic Reagents, clinical Evaluation Pathways and Recommended Clinical Trial Types for Medical Devices, publicly available technical review reports of registered medical device products.

These resources are intended to ensure the scientific integrity and adequacy of clinical evidence.

III. Responsibilities of Applicants

Applicants must strictly fulfill their primary responsibilities, establish and maintain an effective quality management system appropriate to their products, and conduct product design and development oriented towards clinical needs. In accordance with the fundamental principles of medical device safety and performance, applicants must formulate a scientific and rigorous clinical trial protocol after completing research on the rationale for the study and preclinical trial work. When applying for pre-review of the clinical trial protocol, applicants must ensure that all submitted information and materials are truthful, accurate, complete, and traceable, and bear corresponding consequences and legal liabilities.

IV. Conduct of Clinical Trials Based on Pre-Review Opinions

Applicants shall conduct clinical trials in accordance with the pre-review opinions issued by the CMDE. During the clinical trial, if changes occur to the technical characteristics of the product or the content of the clinical trial protocol, the applicant shall assess the impact of such changes on the safety and effectiveness of the medical device and, if necessary, resubmit a request for pre-review of the revised protocol.

Center for Medical Device Evaluation

National Medical Products Administration

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