Announcement on Further Adjustments and Optimizations for the Production of Imported Medical Device Products by Domestic Enterprises in China[1]

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To thoroughly implement the CPC Central Committee and the State Council's strategies on advancing high-level opening-up, fully 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), and to continuously deepen medical device regulatory reform and promote high-quality development of the medical device industry, the following adjustments and optimizations to the Original Announcement are hereby made:

I. Scope of Application

Enterprises mentioned in the Original Announcement may include:

1-Enterprises established by the registrant of the imported medical device;

2-Enterprises that share the same actual controller as the registrant of the imported medical device.

That is, the matters concerning the domestic manufacturing of Class II and Class III medical devices already holding import registration certificates, by foreign-invested enterprises established by or sharing the same actual controller with the registrant of the imported medical device, shall be subject to the provisions of the Original Announcement.

The definition and criteria for "actual controller" shall comply with the relevant provisions of the *Company Law of the People's Republic of China*, i.e., the actual controller refers to a person who, through investment relationships, agreements, or other arrangements, can effectively control the behavior of a company.

II. Registration Application Requirements

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

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(1) Submission Format and Materials

Applicants shall submit registration materials in accordance with: *NMPA Announcement on the Requirements for Medical Device Registration Application Materials and Format of Approval Documents* (2021 No. 121), and *NMPA Announcement on the Requirements for In Vitro Diagnostic Reagent Registration Application Materials and Format of Approval Documents* (2021 No. 122).

Among these, the overview materials, non-clinical data (excluding the checklist of basic safety and performance principles, product technical requirements, and test reports), and clinical evaluation data may utilize the original registration materials from the imported device.

The product technical requirements and test reports must reflect compliance with applicable mandatory national standards.

(2) Verification of Same Actual Controller

If the applicant and the registrant of the imported device share the same actual controller, a statement and supporting documents must be submitted.

These may include:

1-Explanation of shareholding or ownership structure;

2-The most recent annual business report of the applicant containing actual controller information, uploaded or disclosed in accordance with relevant regulatory requirements.

All related materials shall be filed with the drug regulatory authority for recordkeeping.

(3) Authorization from the Import Registrant

The applicant must provide a notarized letter of authorization issued by the registrant of the imported medical device, explicitly permitting the applicant to use the original registration data for the purposes of domestic registration and production. This authorization must be notarized by a notary authority in the country/region where the registrant is located.

III. Quality Management System Inspection Requirements

Applicants must commit that the main raw materials and key manufacturing processes will remain unchanged, and submit a self-inspection report demonstrating compliance of the domestic production with the *Good Manufacturing Practices for Medical Devices*, and a comparative report on the quality management systems between domestic and foreign manufacturing processes.

Drug regulatory authorities will conduct inspections in accordance with procedures for Medical Device Registration Quality System Inspections, with particular focus on the substantial equivalence of the design and development processes across the domestic and foreign quality management systems.

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If any differences exist between the domestic and overseas quality systems for the device to be registered, the applicant must: provide detailed explanations, commit that such differences do not affect the registration requirements, conduct a risk assessment, and Identify key risk points and corresponding control measures to ensure product safety, effectiveness, and quality control.

IV. Other Matters

(1) Priority Processing

For imported innovative medical devices manufactured domestically in accordance with this Announcement, the corresponding registration, production license, and related matters shall be given priority processing.

(2) Domestic Production by Chinese-Invested Overseas Registrants

Where a foreign medical device registrant is invested by a domestic Chinese enterprise, such domestic enterprise, or another domestic enterprise with the same actual controller, may apply to register and manufacture the already-imported Class II or Class III medical device domestically.

(3) Subsequent Regulatory Procedures

For approved products, subsequent applications for registration changes or registration renewals shall be handled in accordance with the *Measures for the Administration of Registration and Filing of Medical Devices* and the *Measures for the Administration of Registration and Filing of In Vitro Diagnostic Reagents*.

National Medical Products Administration

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