**Measures for Further Optimizing Regulatory Services to Support the High-Quality Development of Hainan’s Boao Lecheng International Medical Tourism Pilot Zone**

Recently, Hainan Medical Products Administration, Hainan Provincial Health Commission and Haikou Customs jointly issued a notice on the Measures for Further Optimizing Regulatory Services to Support the High-Quality Development of Hainan Boao Lecheng International Medical Tourism Pilot Zone (hereinafter referred to as "the Measures", and the full text is attached below). The Measures are designed to further improve the business environment in Hainan’s Boao Lecheng International Medical Tourism Pilot Zone, streamline the approval processes for imported drugs and medical devices urgently needed in clinical practice, optimize the approval modes, enhance the efficiency of regulatory services, facilitate the public’s timely access to these urgently needed imported drugs and medical devices, and fuel the high-quality development in the Lecheng Pilot Zone.

The full text of the Measures reads as follows.

To further improve the business environment in the Hainan’s Boao Lecheng International Medical Tourism Pilot Zone, streamline the approval processes for imported drugs and medical devices urgently needed in clinical practice, optimize the approval modes, enhance the efficiency of regulatory services, facilitate the public’s timely access to these urgently needed imported drugs and medical devices, and fuel the high-quality development in the Lecheng Pilot Zone, we have, upon consideration, formulated the following measures.

1. The provincial health administrations shall be responsible for the qualification assessment of medical institutions applying for the use of imported drugs and medical devices urgently needed in clinical practice. Medical institutions can apply for assessment by the individual department according to its capacities. Any medical institution that intends to engage in operational activities with imported drugs and medical devices urgently needed in clinical practice shall apply to the provincial health administrations and meet the following requirements:

(1) The medical institution has obtained a practice license in accordance with the law and has professional departments (including remote diagnosis and treatment teams) within which the applied imported drugs and medical devices would be applicable.

(2) The medical institution shall have the security conditions and management systems that meet the requirements of features and instructions of the urgently needed imported drugs and medical devices for their circulation, transportation, storage and safekeeping.

(3) The medical institution shall establish monitoring systems for adverse reactions to drugs or medical devices, which are staffed by dedicated, professionally trained employees who can adequately perform the duty of monitoring adverse reactions.

(4) The medical institution shall have contingency plans and can handle potentially serious adverse reactions caused by imported drugs or medical devices.

After receiving admissible applications, the provincial health administrations shall, within ten working days, decide whether to allow the concerned departments of the medical institution to carry out operational activities using imported drugs and medical devices urgently needed in clinical practice. Medical institutions qualified for using these urgently needed imported drugs and medical devices are certified as Designated Medical Institutions.

1. The Designated Medical Institution shall submit the types and quantities of imported drugs and medical devices urgently needed in clinical practice depending on targeted indications. The Institution shall submit applications through the Licensed Drugs and Medical Devices Traceability Management Platform and pledges that those drugs and medical devices will be used within the Institution only. The guideline for the application will be issued separately.

3. The provincial health administrations and the medical products administration shall assess and review the Designated Medical Institution's application for imported drugs and medical devices urgently needed in clinical practice.

Upon receiving the application, the provincial health administrations shall complete the assessment within three working days, and the provincial medical products administration shall make administrative decisions on whether to approve the import within seven working days.

After the imported drugs and medical devices urgently needed in clinical practice are approved for use in the Lecheng Pilot Zone for the first time, the subsequent applications shall all be considered as non-first-time applications and can be approved by the administration of medical products in Lecheng.

4. If the management protocols of urgently needed drugs and medical devices imported from overseas differ from those in the Chinese Mainland, then these drugs and medical devices shall be managed according to the protocols approved overseas.

5. The Designated Medical Institution shall commission drug or medical device companies to purchase, import, and distribute the imported drugs and medical devices urgently needed in clinical practice.

The commissioned drug or medical device company (hereinafter referred to as "theCommissioned Company") shall hold a "Business License for Drugs" or "Business License for Medical Devices".

6. The provincial medical products administration and Haikou Customs shall be responsible for the customs clearance of urgently needed imported drugs and medical devices according to the relevant customs regulations and support their electronic customs clearance. The Designated Medical Institution or the Commissioned Company shall not import refurbished medical devices or obtain previously used devices from overseas medical institutions. The import of expired, ineffective, obsolete, or used medical equipment is prohibited.

No import inspection is needed for imported drugs urgently needed in clinical practice. Medical devices and items listed in the Corresponding List of Customs Inspection and Quarantine Names and Commodity Numbers of Special Items shall be subject to administrative licensing in accordance with the relevant customs regulations.

7. The approved imported drugs and medical devices urgently needed in clinical practice shall be regarded as being the same as those imported types approved for registration in the Lecheng Pilot Zone. It is permitted to accept charitable donations of these drugs and medical devices, which shall be managed as imported drugs and medical devices urgently needed in clinical practice.

8. The Designated Medical Institution shall, depending on the patient's condition and safety, confirm whether it is necessary for the patient to take the imported drugs and medical devices out of the Lecheng Pilot Zone. If deemed necessary, the Institution shall formulate out-patient treatment and emergency plans. Once the application is recorded on the Licensed Drugs and Medical Devices Traceability Management Platform, the patient can take doses of drugs or medical devices sufficient for personal use only out of the Lecheng Pilot Zone. The administrative measures for using urgently needed imported drugs and medical devices out of the Lecheng Pilot Zone shall be formulated by the provincial mediacal products administration separately.

9. The provincial medical products administration and the Lecheng Pilot Zone Administration shall establish the Licensed Drugs and Medical Devices Traceability Management Platform to realize the whole-process traceability management of imported drugs and medical devices urgently needed in clinical practice, including the application, procurement, import, distribution, usage, adverse reactions monitoring, etc.

The Designated Medical Institution, the Commissioned Company and the bonded warehouse in the Lecheng Pilot Zone shall manage imported drugs and medical devices urgently needed in clinical practice via the Licensed Drugs and Medical Devices Traceability Management Platform and ensure that the whole process can be traced to responsible entities.

10. If the Designated Medical Institution no longer has the capacity or the conditions to use the imported drugs and medical devices urgently needed in clinical practice, the provincial health administration shall cancel the relevant department’s qualifications to use them.

11. The Designated Medical Institution shall annually assess the safety and effectiveness of using the imported drugs and medical devices urgently needed in clinical practice. It shall report the assessment findings of the preceding year to the provincial health administrations and the provincial medical products administration.

12. After the imported drugs and medical devices urgently needed in clinical practice are approved and marketed in China, if there are still unapproved indications, the drugs and devices can also be applied for use as the imported drugs and medical devices urgently needed in clinical practice, only for the unapproved indications.

13. The Designated Medical Institution is encouraged to introduce insurance mechanisms by purchasing commercial health insurance. If a patient sustains physical injuries from the use of imported drugs or medical devices urgently needed in clinical practice, the Designated Medical Institution shall be held accountable according to national provisions. If the drugs or medical devices themselves cause the injuries, the Designated Medical Institution shall provide compensation before pursuing recourse against responsible units according to related laws or legal agreements.