Administrative Regulation for Import Medical Devices Urgently Needed in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port

Article 1 in order to strengthen the supervision and management of imported medical devices in the international medical tourism pilot area of Boao Le City, Hainan free trade port (hereinafter referred to as the pilot area), and to protect and promote public health, according to the decision of the State Council on suspending the implementation of the regulations on the supervision and administration of medical devices in the international medical tourism pilot area of Boao Le City, Hainan Province (GF [2018] No. 10), These Regulations are formulated in consultation with the State Drug Administration.

Article 2 the special medical institutions (hereinafter referred to as "medical institutions") that use medical devices urgently needed to be imported in the pilot area shall have the domestic leading medical level and meet the following basic conditions:

（1） It has obtained the practice license of medical institution according to law, has grade III grade A conditions, and has professional departments suitable for the clinical urgent need of imported medical devices;

（2） It has facilities and management system for storage and storage that meet the requirements of the characteristics and instructions of imported medical devices in clinical urgent need;

（3） To be trained and trained to monitor and supervise the use of medical devices;

（4） Have the ability of emergency plan and disposal for serious adverse events that may occur in the use of clinical urgently needed imported medical devices;

（5） Pass the relevant qualification evaluation organized by the provincial health management department.

Article 3 the medical team or department that uses the medical device in urgent need of clinical application shall have the domestic leading level in the application field of the product, and its members shall obtain the practicing qualification in the medical institution in the pilot area according to law, have full knowledge of the medical device in urgent need of clinical application, be able to read and correctly understand the original manual, and accept the overseas production of the product before use The guidance and training of enterprises ensure the correct and reasonable use of imported medical devices.

Article 4 if a medical institution is in urgent need of importing medical devices, it shall apply to the provincial health and health administration department for evaluation of clinical urgent need. The provincial health and health administrative department shall, according to the evaluation of clinical urgent imported medical devices and the standards and procedures for the qualification examination of clinical institutions, determine whether the medical devices to be imported are in urgent need of clinical import and the medical institutions are in urgent need of imported medicine Evaluate the use ability of medical devices and provide evaluation opinions.

The standards and procedures for the evaluation of imported medical devices and the qualification examination of clinical institutions shall be formulated by the provincial health and health administration department.

Article 5 if a medical institution is in urgent need of importing medical devices, it shall apply to the provincial drug regulatory department and submit the following materials:

（1） Application form for imported medical devices in clinical urgent need;

（2） Qualification certificate documents;

（3） Product overview;

（4） Description of the necessity of imported medical devices;

（5） Evaluation opinions of provincial health management department;

（6） The use plan and risk management measures of imported medical devices are urgently needed;

（7） Agreements signed between medical institutions and suppliers;

（8） Other materials required by the provincial drug administration.

The medical institution shall track and grasp the dynamic situation of the imported medical devices and patients applied for, and the application materials submitted shall be the latest information. In case of any change of information during the application process, it shall timely report to the provincial drug regulatory department.

Article 6 the provincial drug regulatory department shall organize the evaluation of the application materials, decide whether to approve the import, inform the application medical institutions of the results, and submit the relevant information to the national drug regulatory department on a quarterly basis.

Article 7 in principle, the imported medical instruments in urgent need of clinical use shall be imported from Hainan port through designated legal channels and customs clearance procedures shall be handled by Haikou customs in accordance with the relevant provisions of the state. It is not allowed to import refurbished medical devices or transfer medical devices in use from foreign medical institutions.

If it is really impossible to import through the designated channels due to product reasons, the provincial drug regulatory department shall designate other legal channels for import according to relevant provisions.

Article 8 medical institutions, import agents and bonded warehouses shall strictly implement the relevant provisions of the state, check and keep the relevant supporting documents of the supplier; ask for and keep the bills of the supplier and establish purchase records to ensure that the bills, accounts and goods are consistent; establish and implement the purchase acceptance system and establish a true and complete medical device acceptance record.

The relevant certification documents, purchase records, legal bills and acceptance records of imported medical devices are urgently needed to be kept for 3 years after the expiration date; if the validity period is not specified, the retention period shall not be less than 5 years; the relevant documents and records of implantable medical devices shall be permanently preserved.

Article 9 medical institutions, import agents and bonded warehouses shall carry out transportation and storage according to the characteristics of the clinical urgent need to import medical devices and the requirements of the instructions. Regularly check, check and maintain the medical instruments in stock, monitor and record the temperature and humidity in the storage area, strengthen the management of validity period, and establish corresponding management accounts and maintenance files.

Article 10 medical instruments urgently needed for clinical use shall only be used for specific medical purposes in this medical institution, and shall not be used or installed outside the institution in principle.

For the medical devices that need to be adjusted and maintained outside the hospital, the imported medical devices are allowed to be adjusted and maintained outside the designated medical institutions with the approval of the provincial drug administration department.

Article 11 medical institutions, import agents and bonded warehouses shall strengthen the management of medical instruments and instruments in urgent need in clinical practice, and establish a management system for standby articles.

If a medical institution adjusts and uses the spare parts due to clinical needs, the provincial drug regulatory department shall make an evaluation, and the medical institution shall adjust the use according to the evaluation results.

Article 12 medical institutions shall use imported medical devices in urgent need in accordance with the scope of indications of overseas approved medical devices and corresponding clinical technical specifications, and keep relevant clinical medical records and data. Before use, the patients and their families should be informed of the approved import of the product according to the clinical urgent medical device and the situation of the substitutable product, and sign the informed consent.

After use, it is necessary to follow up and observe each case, carry out clinical use effect evaluation, adverse event monitoring, etc., and report the relevant situation in writing to the provincial health and health administration department and the provincial drug supervision and administration department every quarter.

Article 13 a medical institution shall establish its own reporting system for adverse events of medical devices, and specify that specialized institutions and personnel shall be responsible for the monitoring of adverse events of medical devices.

A medical institution shall actively monitor the import of medical devices in urgent need in clinical practice, and report to the monitoring institution any adverse events that may be related to the clinical urgent need of imported medical devices.

Medical institutions shall establish and keep the adverse event reports and monitoring files of medical devices that are in urgent need of import.

Article 14 medical institutions shall formulate perfect safety prevention measures and risk control plans, introduce insurance mechanism, and immediately start emergency plans in case of emergency, take preventive and control measures and handle them properly in time.

Medical institutions shall track the overseas use of medical devices in urgent need of clinical use. In case of relevant major safety risk early warning, they shall immediately stop using and report to the provincial health and health administration department and the provincial drug supervision and administration department in a timely manner.

If the overseas production enterprise of a product discovers a major safety risk or needs to recall the product, it shall notify the medical institution to stop using the product immediately and take the initiative to recall it. If the imported medical devices are recalled abroad in urgent need, the medical institutions shall stop using them immediately and take appropriate measures to deal with them.

Article 15 a medical institution shall establish and improve its internal quality management system to ensure that the medical team or department has the conditions and ability to meet the requirements of this regulation continuously. If the conditions and capabilities of medical institutions change and no longer meet the requirements or there are other situations that may cause major potential safety hazards, the medical institutions shall take the initiative to stop importing or using the medical devices urgently needed for clinical use, and immediately report to the provincial health and health administration department and the provincial drug supervision and administration department.

The provincial administrative department of health and health and the provincial drug regulatory department shall strengthen the supervision and inspection of medical institutions. If it is found that

the medical institutions do not comply with the provisions or the medical institutions no longer have the ability and conditions to implement the provisions, they shall order the medical institutions to stop the import and use of the medical devices urgently needed in clinical practice.

If the state drug regulatory department finds that it may cause major potential safety hazards and fails to deal with it in time, it may instruct the provincial drug regulatory department to suspend the import and use of medical devices in urgent need.

Article 16 medical institutions shall bear full responsibility for the clinical use of imported medical devices in urgent need. Medical institutions shall be liable for compensation in accordance with the relevant provisions of the state in case of human injury to patients in clinical use. If the injury is caused by the product, the medical institution shall make compensation first, and then claim compensation from the overseas production enterprise according to the law or agreement.

Article 17 the clinical real world data generated by the clinical urgent need of imported medical devices used in the pilot area can be used to apply for the registration of imported products if they meet the relevant requirements of China's medical device registration and declaration.

Medical institutions, manufacturers and other relevant parties should collect clinical real world data legally and regularly.

Article 18 If the imported medical devices in urgent need have been used in the medical institutions for a certain period of time, the provincial drug regulatory department shall inform the overseas manufacturing enterprises to apply for the registration of imported products with the state drug regulatory department and report to the state drug regulatory department. If the registration application is not submitted on time, the import and use in clinical need shall be stopped.

Since the product has obtained the medical device registration certificate, it will no longer be approved for import as a clinical urgent medical device.

Article 19 the provincial health and health administrative department, the provincial drug supervision and administration department, the provincial medical security department, Haikou customs, and the administrative department of the pilot area shall, in accordance with the relevant laws and regulations and these Provisions, perform the relevant management responsibilities for the medical institutions in the pilot area and the medical devices urgently needed to be imported clinically.

The provincial health management department and the provincial drug supervision and administration department explored the establishment and improvement of the joint supervision system and mechanism.

Article 20 the provincial health and health administration department, the provincial drug supervision and administration department, the provincial medical security department, Haikou customs, the provincial big data management department, the leading area management department and other units shall respectively perform the relevant management responsibilities for the research and utilization of clinical real world data in accordance with the corresponding laws and regulations and the provisions.

Article 21 the administrative department of the pilot area shall build a traceability management platform for imported medical devices, and strengthen the supervision of imported medical devices in urgent need by means of information technology.

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