CHINA

New Measures on the Supervision and Administration of Medical Devices Trading

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The National Market Supervision Administration adopted the *Measures on the Supervision and Administration of Medical Devices Trading* ("Measures") on 10 March 2022, which will take effect as of 1 May 2022.

The Measures are promulgated to adapt the newly revised *Regulations on Supervision and Administration of Medical Devices* ("Regulations") issued by the State Council and which took effect as of 1 June 2021. The 2014 version of the *Measures on the Supervision and Administration of Medical Devices Trading* ("Previous Version of Measures") will be repealed as of 1 May 2022.

The Measures implement stricter regulatory requirements and strengthen the supervision and management of medical devices trading enterprises, emphasizing quality management and traceability management throughout the whole business process. Below we introduce main changes compared with the Previous Version of the Measures.

1. Stricter Quality Management Requirements

The Measures provide higher requirements on those enterprises engaging in medical devices trading activities, imposing them to establish a quality management system and quality control measures covering the whole process of medical devices procurement, acceptance, storage, sales, transportation, after-sales service, etc. in accordance with laws and regulations and the Medical Devices Good Supply Practice ("Medical Device GSP"), and keep relevant records (Article 29).

a) Traceability

Article 30 of the Measures provides that medical devices trading enterprises shall establish and implement a product traceability system to ensure product traceability. They shall implement the unique identification system for medical devices in accordance with relevant regulations. We believe this is referring to the *Announcement of the National Medical Products Administration on Issuing the Rules for the Unique Device Identification System for Medical Devices*, with effect from 1

October 2019). The process of unique device identification system for medical devices are being implemented step by step and as of today, the National Products Administration ("NMPA") together with the National Heath Commission and the National Healthcare Security Administration has published the lists of two batches of medical products that are subject to unique device identification system, including all of the Class-III medical devices.

b) Stock-in Inspection

Article 32 of the Measures provides that all medical devices trading enterprises shall establish a stock-in inspection record system. They shall inspect the qualifications of their supplier, as well as medical device registration certificate and filing information, and qualification certificates. The Measures provide for more specific requirements compared with Article 32 of the Previous Version of Measures regarding the content of stock-in inspection records, which shall include:

(1) name, model, specification and quantity of medical device;

(2) medical device registration certificate number or filing number;

(3) names, manufacturing license numbers or filing numbers of the medical device registrant, medical device filing entity and entrusted manufacturing enterprise;

(4) manufacturing batch number or serial number, use period or expiry date, purchase date, etc. of the medical devices;

(5) name, address and contact information of the supplier.

Stock-in inspection records shall be kept for 2 years after the expiry date of medical devices. If there is no validity period, they shall be kept for not less than 5 years. Implantable medical devices stock-in inspection records shall be kept for a permanent term.

c) Entrustment Agreement

(1) Transportation and Storage

If a medical device registrant, a medical device filing entity and a medical device trading enterprise entrusts another entity to transport and store medical devices, it shall evaluate the quality assurance capability of the entrusted party in transporting and storing medical devices, and sign an entrustment agreement with them to clarify the quality of transportation and storage process and to ensure quality and safety during transportation and storage (Article 34).

(2) Sales

If a medical device registrant or a medical device filing entity entrusts another entity to carry out sales, it shall entrust a qualified medical device trading enterprise and sign an entrustment agreement to clarify the rights and obligations of both parties (Article 36).

d) Sales Record

Article 38 of the Measures provides that enterprises engaged in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices shall establish a sales record system. Article 32 of the Previous Version of Measures only generally stipulated that sales record shall be established while the Measures specifically list the items that must be included into the sales record, including:

(1) name, model, specification, registration certificate number or filing number, quantity, unit price, and amount of medical devices;

(2) manufacturing batch number or serial number, use period or expiration date, and sale date of medical devices;

(3) name, manufacturing license number or filing number of medical device registrant, filing entity and entrusted manufacturing enterprise.

For those enterprises engaged in wholesale business of Class II and Class III medical devices, sales records shall also include purchaser's name, address, contact information, relevant license document number or filing number, etc.

Sales records shall be kept for 2 years after the expiry date of medical devices. If there is no validity period, they shall be kept for not less than 5 years. Implantable medical devices sales records shall be kept for a permanent term.

e) Adverse Event Monitoring

Article 41 of the Measures provides that medical device trading enterprises shall assist medical device registrants and filing entities to carry out adverse event monitoring, and report to medical device adverse event monitoring technical institution in accordance with the regulations of drug administrative authorities. This obligation of assistance is in line with Article 16 of the *Administrative Measures for Medical Device-Related Adverse Event Monitoring and Re-evaluation* (with effect from 1 January 2019).

f) Cessation of Trading

It is newly stipulated in Article 42 of the Measures that if a medical device trading enterprise finds out that the medical device it trades does not meet mandatory standards, its registered or filed product technical requirements, or has other defects, it shall immediately cease trading, notify medical device registrant, filing entity and other relevant units, and record the information of notification and cessation of trading.

g) Quality Management Self-inspection

Article 40 of the Previous Version of the Measures only required that Class-III medical devices trading entities shall establish a self-inspection system and submit an annual self-inspection report to drug administrative authorities before the end of each year. Article 44 of the Measures now requires that all the medical device trading enterprises shall establish a quality management self-inspection system, conduct self-inspection in accordance with the requirements of the Medical Devices GSP Standard, and submit the previous year’s self-inspection report to the local city and county-level drug administrative authorities before 31 March of each year.

2. Adjustment in Formalities for License o r Record-Filing

The Measures adjust the formalities for obtaining medical devices trading license or record-filing. The main adjustments are described as below:

a) Documents submitted for Class-II Medical Devices Trading record-filing application

Article 23 of the Measures provides that for the same entity who wants to apply for Class III Medical Devices Trading License and Class II Medical Devices Trading Record-filing at the same time, or for an entity who has obtained a Class III Medical Devices Trading License and wants to apply for Class II Medical Devices Trading Record-filing, it will be exempted from submitting relevant materials for Class II Medical Devices Trading Record-filing.

b) Exemption from record-filing

Article 25 of the Measures provides that for Class II medical devices whose product safety and effectiveness are not affected by distribution process, record-filing can be exempted. The specific list of products of which record-filing can be exempted shall be formulated, adjusted and published by the NMPA. Although this provision is newly added in the Measures compared with the Previous Version of Measures, this regime has been already included in the Regulations. We noticed that on 28 June 2021, to implement the Regulations, the NMPA already published such list and implemented exemption from record-filing of those products falling into that list.

c) Re-registration of Class III Medical Devices Trading License

Article 16 of the Measures provides that for re-registration of Class III Medical Devices Trading License, the applicant shall file a re-registration application **between 90 working days and 30 working days** prior to the expiration of the validity period of the license. This term is shorter than the "six months prior to expiration of the license" as required by Article 22 of the Previous Version of the Measures. If the re-registration application is not submitted within the time limit, re-registration application will be rejected.

3. Stricter Supervision Measures

The Measures introduce a set of supervision measures which are stricter than those contained in the Previous Version of the Measures.

a) Classification and Grading Management

Article 47 of the Measures stipulates that drug administrative authorities shall implement classification and grading management system according to the quality management of medical device trading enterprises and the risk level of the medical device products, and will dynamically adjust it.

b) Key Supervision and Inspection Target

The following kinds of medical device trading enterprises shall be treated as key supervision and inspection targets according to Article 52 of the Measures:

(1) Serious problems were found in the supervision and inspection of the previous year;

(2) Those who are subject to administrative penalties for violating relevant laws and regulations;

(3) The key inspection enterprises determined by the risk consultation[1];

(4) Those enterprises with bad credit records [2];

(5) Newly established medical device wholesale enterprises and Class-III medical device retail enterprises whose trading conditions have undergone major changes;

(6) Specially providing storage and transportation services for other medical device registrants, filing entities, and production and trading enterprises;

(7) Other situations requiring key supervision and inspection.

c) Extension of Inspection

Article 54 of the Measures newly provides that according to the needs of medical device quality and safety risk prevention and control, drug administrative authorities have the right to extend their inspections on other relevant units and individuals that provide products or services for medical device trading activities.

d) Emergency Control Measures

Article 57 of the Measures provides that if traded medical devices cause harm to human body or it is proven that it may endanger human health, drug administrative authorities may take emergency control measures to suspend import, trading and use, and issue safety warning information. Moreover, if during the supervision and inspection, it is found that trading activities seriously violate medical device trading quality management regulations, cannot guarantee the safety and effectiveness of the products, and may endanger human health, drug administrative authorities are entitled to take the same measures as mentioned above. We noticed that this newly added provision is in line with Article 72 of the Regulations.

4. Heavier Legal Liabilities

Except for those acts of violation that are subject to the relevant clauses concerning legal liabilities set forth in the Regulations, the Measures intensify the punishment on those acts specifically regulated under the Measures.

a) Article 66 of the Measures provides that under any of the following circumstances, the entity shall be ordered to make corrections within a time limit. A fine of not less than 10,000 RMB but not more than 50,000 RMB shall be imposed. In serious circumstances, a fine of not less than 50,000 RMB but not more than 100,000 RMB shall be imposed. If harmful consequences are caused, a fine of not less than 100,000 RMB but not more than 200,000 RMB shall be imposed:

(1) The **Class-III medical device trading enterprise changes its business premises, business scope, business method, and warehouse address without authorization**;

(2) After the expiration of the validity period of the medical device trading license, the relevant entity continues to engage in medical device trading activities without going through the re-registration procedures in accordance with the law.

b) Article 68 of the Measures provides that if a medical device trading enterprise fails to submit its annual self-inspection report of the quality management system as required, or violates the provisions of these Measures to provide storage and transportation services for other medical device manufacturing and trading enterprises, drug administrative authorities shall order corrections within a time limit. If it refuses to make corrections, a fine of not less than 10,000 RMB but not more than 50,000 RMB shall be imposed. In serious circumstances, a fine of not less than 50,000 RMB but not more than 100,000 RMB shall be imposed.

c) Article 69 of the Measures provides that if a **Class III medical device trading enterprise** fails to change the **enterprise name, legal representative and person in charge** in accordance with the provisions of the Measures, drug administrative authorities shall order corrections within a time limit. If it refuses to make corrections, a fine of not less than 5,000 RMB but not more than 30,000 RMB shall be imposed.

Medical devices trading enterprises should follow the new requirements contained in the Measures to achieve full compliance.

[1]According to Article 58 of the Measures, drug administrative authorities shall conduct regular risk consultations, research and judgments based on the supervision and inspection, product sampling inspection, adverse event monitoring, complaints and reporting, and administrative penalties. This implies that by risk consultations, drug administrative authorities can evaluate the risk level of each medical devices trading enterprise.

[2]According to Article 60 of the Measures, drug administrative authorities at the city level (with

districts) shall establish and update the credit files of medical devices trading enterprises within their jurisdiction in a timely manner. The credit file shall include information, such as license and/or record-filing of the medical device trading enterprise, results of supervision and inspection, investigation and punishment of illegal acts, random quality inspections, self-inspection reports, records of bad behaviors, and complaints and reports.

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