Measures for the Administration of Imported Medicinal Materials

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Order of the State Administration for Market Regulation No. 9

May 16, 2019

The Measures for the Administration of Imported Medicinal Materials, deliberated and adopted at the 8th executive meeting 2019 of the State Administration for Market Regulation on April 28, 2019, are hereby issued and shall go into force as of January 1, 2020.

Director General Zhang Mao

Measures for the Administration of Imported Medicinal Materials

(Issued with Order of the State Administration for Market Regulation No. 9 on May 16, 2019)

Chapter I General Provisions

Article 1 The Measures are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Implementing Regulations of the Drug Administration Law of the People's Republic of China and other pertinent laws and administrative regulations for the purpose of strengthening the supervision and administration of imported medicinal materials and guaranteeing the quality of imported medicinal materials.

Article 2 The Measures shall apply to the application for, the examination and approval of, the filing, port inspection, supervision and administration of imported medicinal materials.

Article 3 Medicinal materials must be imported via such ports permitting the import of drugs or such border ports permitting the import of medicinal materials as approved by the State Council.

Article 4 The National Medical Products Administration (hereinafter referred to as "NMPA") shall be in charge of the supervision and administration of the import of medicinal materials all over the country. The NMPA may appoint the medical product administrations of provinces, autonomous regions and municipalities directly under the Central Government (hereinafter referred to as "provincial medical product administrations") to examine and approve the initially imported medicinal materials, and shall conduct supervision and direction of the examination and approval of the initially imported medicinal materials.
The provincial medical product administrations shall supervise and administrate the imported medicinal materials according to pertinent laws and, to the extent appointed, conduct examination and approval of the initially imported medicinal materials in the name of the NMPA.
The medical product administration at the locality of a port permitting the import of drugs or a border port permitting the import of medicinal materials (hereinafter referred to as "port medical product administration") shall be in charge of the filing of imported medicinal materials, and organize, supervise and administrate port inspections.

Article 5 For the purpose of the Measures, "Medicinal Material Importer" refers to an applicant for examination and approval of initially imported medicinal materials or an entity applying for filing of imported medicinal materials.

A medicinal material importer shall be a person holding the marketing approval of Chinese patent drugs, a traditional Chinese medicine manufacturing enterprise or a drug operation enterprise of which the business scope covers the operation of Chinese medical herbs or traditional Chinese medicine decoction pieces.

Article 6 Initially imported medicinal materials shall be reported to the port medical product administration for filing after the approval document for the import of medicinal materials is obtained according to the Measures. "Initially Imported Medicinal Material" refers to the medicinal material imported not from the same country (region), not by the same applicant or not concerning the same medicinal material origin. Non-initially imported medicinal materials shall be reported directly to the port medical product administration for filing according to the Measures. Non-initially imported medicinal materials shall be subject to catalog management. Specific catalogs shall be formulated and adjusted by the NMPA. Those medicinal materials that have not been included in the catalogs, of which applicants, medicinal material origins or countries (regions) remain unchanged, shall be subject to administration as non-initially imported medicinal materials.

Article 7 Imported medicinal materials shall conform to the state drug standards. The breeds not embodied in the current edition of the Chinese Pharmacopoeia shall be subject to the standards for imported medicinal materials. The breeds not embodied in the current edition of the Chinese Pharmacopoeia and the standards for imported medicinal materials shall be subject to other state drug standards. Those medicinal materials habitually used for the drugs of ethnic minorities which are imported by minority nationality regions, in the case of absence of applicable state drug standards, shall conform to corresponding standards for medicinal materials of relevant provinces and autonomous regions.

Chapter II Application for, Examination and Approval of Initial Import of Medicinal Materials

Article 8 In the case of the initial import of medicinal materials, the applicant shall complete the application form for the import of medicinal materials via the information system of the NMPA (hereinafter referred to as "information system") and submit the following materials to the local provincial medical product administration:
1. application form for the import of medicinal materials;
2. copy of the applicant's permit for pharmaceutical manufacture or permit for drug operation; if the applicant holds the marketing approval of Chinese patent drugs, a copy of the relevant drug approval document shall be provided;
3. copy of the exporter's subject registration certification;
4. copy of the purchase contract, as well as the notarial deed;
5. such information as ecological environment of the place of origin of the medicinal material, resource reserve, wild, planting or breeding status, collection and primary processing in the place of origin;
6. standards for medicinal materials, and source thereof; and
7. original of the identification certification of medicinal material origins issued by the agency within the territory of China qualified for identification of animal and plant origins, containing such information as identification basis, identification conclusion, pictures of sample, identifier, identifying agency and its common seal.
The applicant shall be responsible for the authenticity of the declaration materials.

Article 9 After receiving the declaration materials of initially imported medicinal materials, the provincial medical product administration shall carry out formal examination of the normalization and completeness of the declaration materials. In the case of any errors in the declaration materials which can be corrected there and then, the applicant shall be permitted to make corrections immediately. Where the declaration materials are incomplete or are not prepared in the statutory format, the applicant shall be notified of all contents to be supplemented and corrected immediately or within five days once thereafter; in the case of non-notification beyond the specified period, the declaration materials shall be deemed to be accepted on the date of their receipt.
The provincial medical product administration shall issue a notice of acceptance or rejection if it decides to accept or reject the application for the initial import of medicinal materials. In the case of rejection, a written statement shall be made, presenting relevant causes.

Article 10 An applicant shall, after receiving the notice of acceptance of the application for the initial import of medicinal materials, in due time submit the samples to the local provincial drug inspection institution for inspection and, meanwhile, submit the materials as mentioned in Article 8 hereof.

Article 11 The provincial drug inspection institution shall, within 30 days after receiving the samples for inspection and relevant materials, complete the sample inspection, issue the report on inspection of

imported medicinal materials to the applicant and submit it to the provincial medical product administration. In the case of necessary extension of the inspection period due to varietal characteristics, inspection items and other reasons, the extended period and relevant causes shall be reported to the provincial medical product administration in writing and notified to the applicant.

Article 12 In the case of objections to the inspection result, the applicant may apply for reinspection according to the Drug Administration Law. The drug inspection institution shall, within 20 days after accepting the application for reinspection, make the reinspection conclusion, report it to the provincial medical product administration and inform the applicant of the conclusion.

Article 13 Where, in the process of examination and approval, the provincial medical product administration deems that more documents shall be supplemented by the applicant, it shall require the same once and for all.
The applicant shall supplement all materials once as required within four months after receiving the notice of supplementary materials; otherwise, failure to supplement the required materials beyond the specified period shall result in a decision of rejection. Where no supplementary materials can be provided within the specified period as a result of force majeure, the applicant shall submit an application for extension to the local provincial medical product administration, stating relevant causes.

Article 14 A provincial medical product administration shall, within 20 days after accepting the application, make a decision to approve or reject the application. If all conditions are satisfied, the one-off approval document for the import of medicinal materials shall be issued. The period spent on inspection and supplementation of relevant materials shall be exclusive of the time limit of examination and approval.

Article 15 In the case of changes in the approved items concerning the approval document for the import of medicinal materials, the applicant shall complete the supplementary application form for the import of medicinal materials via the information system and submit the supplementary application to the provincial medical product administration issuing the original approval document. An applicant submitting the supplementary application shall be the person holding the original approval document for the import of medicinal materials and shall submit the following materials:
1. supplementary application form for the import of medicinal materials;
2. original of the approval document for the import of medicinal materials; and
3. materials concerning the items to be changed.
Besides the materials as mentioned in the first paragraph, the applicant changing its name shall submit the copy of the applicant's permit for pharmaceutical manufacture or permit for drug operation and the copy of the page of change records, or the copy of the drug approval certification and the approval document for the supplementary application for change of the holder's name.
Besides the materials as mentioned in the first paragraph, the applicant changing the port of arrival shall submit a copy of the purchase contract and relevant notarial deed.

Article 16 A provincial medical product administration shall, within 20 days after accepting the supplementary application, complete the examination and approval thereof. If the application is acceptable, the approval document for the supplementary application for the import of medicinal materials shall be issued.

Article 17 If a provincial medical product administration decides to approve the application, it shall serve the approval document for the import of medicinal materials or the approval document to the supplementary application for the import of medicinal materials to the applicant within ten days after making the decision of approval. If the provincial medical product administration decides to reject the application, it shall serve the notice of examination opinions on the applicant within ten days after making the decision of rejection, stating relevant causes and indicating that the applicant has the right to apply for administrative reconsideration or file an administrative lawsuit according to pertinent laws.

Chapter III Filing

Article 18 An applicant for the initial import of medicinal materials shall, within one year after obtaining the approval document for the import of medicinal materials, organize to import the medicinal materials from the port of arrival as indicated in the approval document for the import of medicinal materials.

Article 19 An importer shall report the import of medicinal materials to the port medical product administration for filing, complete the application form for the inspection of imported medicinal materials via the information system and submit the following materials:

1. original of the application form for the inspection of imported medicinal materials;
2. copy of the certificate of origin;
3. standards for medicinal materials and source thereof;
4. copies of the packing list, bill of lading and freight invoice;
5. as for imported medicinal materials which are transited via other countries (regions), copies of all materials from the place of origin to each entrepot, including purchase contracts, packing lists, bills of lading and freight invoices; and
6. if the imported medicinal materials concern relevant endangered species of wild fauna and flora, the import and export of which are restricted according to the Convention on International Trade in Endangered Species of Wild Fauna and Flora, a copy of the certification permitting import & export issued by the Endangered Species Import and Export Management Office shall also be provided.
Besides the materials as mentioned in the first paragraph, the applicant for filing of initially imported medicinal materials shall submit copies of the approval document for the import of medicinal materials and the approval document for supplementary application for the import of medicinal materials (if any).
Besides the materials as mentioned in the first paragraph, the applicant for filing of non-initially imported medicinal materials shall submit a copy of the importer's permit for pharmaceutical manufacture or permit for drug operation, a copy of the exporter's certification of subject registration, a copy of the purchase contract and relevant notarial deed. If an exporter holds the marketing approval for Chinese patent drugs, it shall submit a copy of the approval certification of relevant drugs.

Article 20 The port medical product administration shall carry out the formal examination of the completeness and normalization of the filing materials. If the materials are acceptable, the port medical product administration shall issue the customs clearance form for imported drugs, take back the approval document for the initial import of medicinal materials and, meanwhile, send the notice of port inspection of imported medicinal materials to the port drug inspection institution, together with one copy of filing materials.

Article 21 An exporter shall go through the procedures for customs declaration and release with the Customs using the customs clearance form for imported drugs.

Chapter IV Port Inspection

Article 22 The port drug inspection institution shall, within two days after receiving the notice of port inspection of imported medicinal materials, agree with the importer on the time of on-site sampling and carry out on-site sampling on schedule at the designated stock place. At the time of on-site sampling, the importer shall produce the original of the certificate of origin of the medicinal materials.

Article 23 The port drug inspection institution shall check whether the original of the certificate of origin of the medicinal materials, and the medicinal materials arrived at the port are consistent with the filing materials provided by the port medical products administration. If the documents and medical materials are acceptable, it shall carry out the sampling, complete a list of sampling records on the imported medicinal materials, indicate the word "sampled" on the original of the customs clearance form for imported drugs of the importer, and affix the common seal of the sampling entity to it. If the documents and medical materials are not acceptable, it shall refuse to carry out the sampling, and inform the local port medical product administration of the decision within two days thereafter.

Article 24 The port drug inspection institution shall complete the inspection within 20 days after the sampling, and issue an inspection report on the imported medicinal materials. If it is unable to complete the inspection on schedule due to objective reasons, it shall notify the importer and the port medical product administration of the extended period and causes in a written form.
The port drug inspection institution shall submit the inspection report on imported medicinal materials to the port medical product administration and notify the importer.
Imported medicinal materials may not be sold and used until they pass the port inspection

Article 25 Where an importer has any objection to the inspection result, it may apply for reinspection in accordance with the Drug Administration Law. The drug inspection institution shall, within 20 days after accepting the application for reinspection, draw the reinspection conclusion, report it to the port medical product administration and notify the importer.

Chapter V Supervision and Administration

Article 26 After receiving the notice of non-sampling of imported medicinal materials, the port medical

product administration shall take compulsory administrative measures such as sealing up and seizure of all medicinal materials which relevant evidence proves may be dangerous to human health and, of which the procedures for Customs inspection and release have been completed, and make the decision within seven days.

Article 27 As for those imported medicinal materials which are found to fail to meet the standards through inspection and, of which the procedures for Customs inspection and release have been completed, the port medical product administration shall, after receiving the inspection report, in due time take compulsory administrative measures such as sealing up and seizure, make a decision according to the pertinent laws and report to the local provincial medical product administration the relevant measures.

Article 28 The NMPA shall, if necessary, organize an overseas inspection of the place of origin, primary processing and other production fields concerning imported medicinal materials. Relevant importers of medicinal materials shall coordinate exporters to cooperate in such inspection.

Article 29 When a person holding the marketing approval of Chinese patent drugs, a traditional Chinese medicine manufacturing enterprise or a drug operation enterprise procures imported medicinal materials, the copy of the inspection report on imported medicinal materials which is issued by the port drug inspection institution and the copy of the customs clearance form for imported drugs which bears such word "sampled" and the common seal shall be examined, and relevant provisions on drug traceability management shall be implemented strictly.

Article 30 The packing of imported medicinal materials must meet the quality requirements for imported medicinal materials, and be suitable for storage, transportation and import inspection. On each package such information as Chinese name, serial number of the approval document (except for non-initially imported medicinal materials), place of origin, shipping mark, importer's name, exporter's name, port of arrival, weight and date of processing or packing with respect to the medicinal material must be indicated.

Article 31 Information such as acceptance of the applications for the import of medicinal materials, the results of examination and approval, the acts in violation of pertinent laws and regulations and relevant punishments shall be publicized on the website of the NMPA.

Chapter VI Legal Liability

Article 32 Where any importer obtains any approval document for the initial import of medicinal materials by providing false certifications, documentations or samples or resorting to other tricks, it shall be subject to punishment in accordance with the Drug Administration Law and other pertinent laws and regulations.

Article 33 Where any importer applies for filing by providing false certifications or documentations or resorting to other tricks, a warning and a fine of more than CNY10,000 but less than CNY30,000 shall be imposed upon it.

Chapter VII Supplementary Provisions

Article 34 The serial number of the approval document for the import of medicinal materials shall be in the following format: (abbreviations of the province, autonomous region or municipality directly under the Central Government) Yao Cai Jin Zi + 4 digits of reign title + 4 digits of sequence number.

Article 35 The Measures shall go into force as of January 1, 2020. The Measures for the Administration of Imported Medicinal Materials (for Trial Implementation) issued on November 24, 2005 by the former State Food and Drug Administration shall be abolished simultaneously.