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स्वच्छ भारत

कृषि और प्रसंस्कृत खाद्य उत्पाद
निर्यात विकास प्राधिकरण
(वाणिज्य एवं उद्योग मंत्रालय, भारत सरकार)

Agricultural and Processed Food Products Export Development Authority
(Ministry of Commerce & Industry, Govt.of India)

ADVISORY

FFV-2021-22-00071 Date: 14.07.2022

The General Administration of Customs of China (GACC) has informed that exporters can directly export products used in **Traditional Chinese Medicine (TCM)** without requiring any registration with GACC. GACC had informed the Embassy of India, Beijing that TCM products category had been shifted from the Import and Export Food Safety Bureau of GACC to the Department of Animal and Plant Quarantine of GACC.

As per the GACC, according to the Measures for the Administration of Imported Medicinal Materials, products used in TCM must be imported via such ports or such borders which permit the import of medicinal materials as approved by the State Council of China. The list of ports is attached as **Annexure I**.

GACC has also informed that the **importers** of TCM products **should contact the local customs to understand the customs declaration procedures before importing from foreign countries.**

The customs declaration process for TCM products is as follows:

i. Importer should get listed for import of TCM products with China Customs. (Please refer to attached two measures for details) **(Annexure II & III)**
ii. Importer should get Drug Import Customs Clearance issued by the local office of National Medicinal Products Administration of China (NMPA).

Further, it may please be noted that for homologous products which can be **used both as a food product (spices etc.) and as a TCM product**, if declared as food product, Indian enterprises are to first, register with GACC for export of the food product (as per GACC order No. 248, 249) on China Import Food Enterprises Registration System and second, ensure their importer can arrange a certificate for 'Non-requirement of Customs Clearance for Drugs' from the local NMPA for customs clearance procedures. It has also been informed that at present, Nanning customs of Guangxi Province is being authorized to provide facilitation to enterprises. If the importer is registered in the Guangxi Province and are non-TCM products handling enterprise, Nanning NMPA can issue a notice for 'Non-requirement of Customs Clearance for Drugs' and the enterprise can apply for customs clearance for such homologous food products with this notice.

An article on Analysis of quarantine of imported Chinese medicinal materials published on GACC's official Wechat account is also enclosed for reference. **(Annexure IV)**

Exporters are advised to follow the requirement for export of TCM products to China.

U.K. Vats
General Manager

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ANNEXURE I

List of ports permitting the import of TCM products is as follows:

i. Heihe Port in Heilongjiang Province
ii. Dongning port in Heilongjiang Province
iii. Ji'an port in Jilin Province
iv. Changbai port in Jilin Province
v. Tumen port in Jilin Province
vi. Sanhe port in Jilin Province
vii. Erenhot port in Inner Mongolia Autonomous Region
viii. Manzhouli Port in Inner Mongolia Autonomous Region
ix. Pingxiang Port of Guangxi Zhuang Autonomous Region
x. Dongxing port of Guangxi Zhuang Autonomous Region
xi. Longbang port of Guangxi Zhuang Autonomous Region
xii. Ruili port of Yunnan Province
xiii. Tianbao port of Yunnan Province
xiv. Jinghong port of Yunnan Province
xv. Hekou port of Yunnan Province
xvi. Alashankou port of the Xinjiang Uygur Autonomous Region
xvii. Horgos port of the Xinjiang Uygur Autonomous Region
xviii. Turgat port of the Xinjiang Uygur Autonomous Region
xix. Hongqi Lafu port of the Xinjiang Uygur Autonomous Region
xx. Zhangmu port of the Tibet Autonomous Region
xxi. Jilong port of the Tibet Autonomous Region
xxii. Pulan port of the Tibet Autonomous Region
xxiii. Aidian port of Chongzuo city of the Guangxi Zhuang Autonomous Region.

ANNEXURE II

Measures for quarantine supervision and administration of imported and exported Chinese medicinal materials

Measures for quarantine supervision and administration of imported and exported Chinese medicinal materials (revised in November 2018)

Order of the General Administration of Customs No. 243

November 23, 2018

Chapter I General Provisions

Article 1 These measures are formulated in accordance with the provisions of the law of the people's Republic of China on entry and exit animal and plant quarantine and its implementation regulations and other laws and regulations in order to strengthen the supervision and administration of the quarantine of Chinese medicinal materials entering and leaving the country, prevent the spread of animal and plant epidemics into and out of the country, protect the production of agriculture, forestry, animal husbandry, fishery and human health, and protect ecological security.

Article 2 the term "traditional Chinese medicine" as mentioned in these Measures refers to the raw materials of medicinal plants and animals, which are formed after primary processing after harvesting.

Article 3 these measures are applicable to the quarantine, supervision and administration of imported and exported Chinese medicinal materials declared as medicinal materials.

The inspection, quarantine and supervision and administration of imported and exported Chinese medicinal materials declared for consumption shall be carried out in accordance with the provisions of the General Administration of Customs on imported and exported food.

Article 4 the General Administration of Customs shall be responsible for the unified administration of the quarantine, supervision and administration of imported and exported Chinese medicinal materials throughout the country.

The competent customs is responsible for the quarantine, supervision and administration of imported and exported Chinese herbal medicines in the areas under its jurisdiction.

Article 5 the General Administration of Customs implements the application system for the entry and exit of traditional Chinese medicinal materials. When traditional Chinese medicine materials enter or leave the country, the enterprise shall declare the intended use to the competent customs, specifying "medicinal" or "edible".

Chinese medicinal materials declared as "medicinal" should be listed in the catalogue of medicinal materials in the Pharmacopoeia of the people's Republic of China. Chinese medicinal materials declared as "edible" shall be articles that can be used for food according to national laws, administrative regulations, rules and documents.

Article 6 the General Administration of Customs shall implement risk management on inbound and outbound Chinese medicinal materials; Implement registration management for overseas production, processing and storage units (hereinafter referred to as overseas production enterprises) that export Chinese herbal medicines to China; According to the requirements of the importing country or region, the production, processing and storage units of outbound Chinese medicinal materials (hereinafter referred to as outbound production enterprises) shall be subject to registration management; Implement integrity management for the production and management enterprises of inbound and outbound Chinese medicinal materials.

Article 7 inbound and outbound Chinese herbal medicine enterprises shall engage in production, processing and business activities in accordance with laws, administrative regulations and relevant standards, bear the main responsibility for epidemic prevention, be responsible to the society and the public, ensure the safety of inbound and outbound Chinese herbal medicine, actively accept supervision and bear social responsibility.

Chapter II entry quarantine supervision

Article 8 the General Administration of Customs implements a quarantine access system for imported Chinese medicinal materials, including product risk analysis, evaluation and examination of the regulatory system, determination of quarantine requirements, registration of overseas production enterprises, and entry quarantine.

Article 9 the General Administration of Customs shall conduct product risk analysis and regulatory system assessment on the countries or regions that export Chinese herbal medicines to China for the first time, and conduct a retrospective review on the countries and regions that have already traded.

Based on the results of risk analysis, assessment and examination, the General Administration of Customs shall negotiate with the competent authorities of the exporting country or region to determine the quarantine requirements for the export of Chinese herbal medicines to China, negotiate and sign relevant protocols, and determine the quarantine certificate.

The General Administration of customs is responsible for formulating, adjusting and publishing on the website of the General Administration of customs the list of countries or regions that are allowed to enter the territory of Chinese herbal medicines and the types of products.

Article 10 the General Administration of Customs shall, based on the results of the risk analysis, determine the catalogue of varieties of Chinese medicinal materials that need to be registered by overseas production, processing and storage units, and implement dynamic adjustment. The registration review procedures and technical requirements shall be separately formulated and issued by the General Administration of customs.

The General Administration of Customs shall register the overseas production enterprises of Chinese medicinal materials listed in the catalogue. The registration is valid for 4 years.

Article 11 overseas production enterprises shall meet the requirements of the laws and regulations of the exporting country or region and the mandatory requirements of China's national technical specifications.

Article 12 when applying for registration in China, the competent authorities of the exporting country or region shall examine the overseas production enterprises, and recommend them to the General Administration of Customs after meeting the relevant provisions of Articles 10 and 11 of these measures, and submit the following materials in Chinese or both Chinese and English:

（1） Relevant laws and regulations on animal and plant epidemics, veterinary health, public health, plant protection, enterprise registration management, etc. in the country or region where they are located, and written materials on the institutional setup and personnel of the competent department in the country or region where they are located, as well as the implementation of laws and regulations;

（2） List of overseas production enterprises applying for registration;

（3） The assessment conclusion of the competent department of the country or region where it is located on the actual situation of epidemic prevention and health control of the enterprise it recommends;

（4） A statement that the enterprise recommended by the competent department of the country or region where it is located meets the requirements of Chinese laws and regulations;

（5） Application for enterprise registration, plan of factory, workshop and warehouse, process flow diagram, animal or plant quarantine prevention and control system documents, photos of epidemic prevention and disinfection treatment facilities, photos of harmless treatment facilities of waste and packaging, etc.

Article 13 after receiving the recommendation materials and passing the written examination, the General Administration of Customs may, after consultation with the competent department of the exporting country or region, send personnel to the exporting country or region to evaluate its supervision system and inspect the overseas production enterprises applying for registration.

The applicant enterprises that meet the requirements after inspection shall be registered.

Article 14 for overseas production enterprises that have obtained registration and need to be renewed, the competent department of the exporting country or region shall apply to the General Administration of Customs in accordance with Article 12 of these measures six months before the expiration of the term of validity. The General Administration of Customs may send personnel to the exporting country or region to review its supervision system and inspect the overseas production enterprises that apply for it.

For countries or regions that meet the requirements in the retrospective review, overseas production enterprises that meet the requirements after inspection shall be registered, and the period of validity shall be extended for 4 years.

Article 15 Where the entry of traditional Chinese medicinal materials requires the approval of entry animal and plant quarantine, the owner or his agent shall obtain the entry animal and Plant Quarantine License of the people's Republic of China in accordance with the provisions of the measures for the administration of entry animal and plant quarantine approval before signing the trade contract.

Article 16 the General Administration of Customs may, according to actual needs, send personnel to the exporting country or region for pre inspection with the consent of the competent government departments of the exporting country or region.

Article 17 before or at the time of the entry of traditional Chinese medicinal materials, the owner or his agent shall apply to the Customs at the port of entry for inspection with the following materials:

（1） The quarantine certificate issued by the authorities of the exporting country or region that meets the requirements of the General Administration of customs;

（2） Certificate of origin, trade contract, bill of lading, packing list, invoice.

Article 18 the customs shall examine the relevant documents submitted by the owner or his agent, and accept the inspection application if it meets the requirements.

If there is no valid quarantine certificate issued by the animal and plant quarantine institution of the government of the exporting country or region, registration is required, registration is not handled as required, or quarantine approval procedures are not handled according to law, the customs may return or destroy them according to the specific circumstances.

Article 19 the customs shall implement quarantine of imported Chinese medicinal materials in accordance with the provisions of Chinese laws and regulations and the requirements of national mandatory standards, the requirements listed in the entry animal and Plant Quarantine License, and the quarantine requirements determined in Article 9 of these measures.

Article 20 the Customs at the port of entry shall carry out on-site quarantine in accordance with the following provisions:

（1） Inquire the time of departure and port, countries or regions passing through, loading list, etc., and check whether the documents are true and valid, and whether the documents are consistent with the name, quantity (weight) of the goods, exporting country or region, shipping mark, mark, name of overseas production enterprise, registration number, etc;

（2） Whether the package is in good condition, whether it has animal and plant packaging and bedding materials, and whether it complies with the provisions of the law of the people's Republic of China on entry and exit animal and plant quarantine and its implementation regulations, and the measures for the supervision and administration of the quarantine of wood packaging of imported goods;

（3） Whether the traditional Chinese medicine has corruption and deterioration, whether it carries pests, animal excreta or other animal tissues, and whether it carries animal carcasses, soil and other prohibited substances.

Article 21 in case of any of the following circumstances during on-site inspection, the customs shall issue a notice of quarantine treatment and carry out corresponding quarantine treatment:

（1） Those that are prohibited from entering the country by laws and regulations, those with prohibited goods, those with inconsistent cargo certificates, and those found to be seriously corrupt and deteriorated shall be returned or destroyed;

（2） If the package is damaged, the owner or his agent shall be responsible for sorting it out completely before unloading it from the means of transport. The customs shall carry out quarantine treatment on the contaminated sites, articles and instruments;

（3） Those with harmful organisms, animal excreta or other animal tissues shall be subject to quarantine treatment in accordance with relevant regulations;

（4） For those polluted by diseases and pests or suspected of being polluted by diseases and pests, the relevant goods shall be sealed up, and the contaminated goods, loading and unloading tools and sites shall be disinfected.

Article 22 If diseases and insect pests or symptoms of diseases and insect pests are found during on-site quarantine, or laboratory quarantine is required according to relevant working procedures, the customs shall sample the imported traditional Chinese medicinal materials and send them to the laboratory.

Article 23 before obtaining the quarantine certificate, traditional Chinese medicinal materials shall be stored in a place approved by the customs. Without the permission of the customs, no unit or individual may transfer, sell or process them without authorization.

The entry animal and Plant Quarantine License states that the product is subject to quarantine and processing supervision by the destination customs, and the port customs will issue an entry goods transfer notice after verification and inspection and disinfection of the outer package. The consignee or his agent will apply for quarantine at the destination customs within the specified time limit. Without quarantine inspection, it shall not be sold or processed.

Imported Chinese medicinal materials that need entry quarantine approval shall be stored and processed in the designated enterprises listed in the quarantine approval permit.

Article 24 imported Chinese medicinal materials can be sold, used, stored or processed in designated enterprises only after they have passed the quarantine inspection and the Customs has issued the inspection and quarantine certificate of Inbound Goods. The inspection and quarantine certificate of Inbound Goods shall list the name of the goods, country or region of origin, quantity / weight, production batch number / production date, purpose, etc.

Article 25 If the goods fail to pass the quarantine inspection, the customs shall issue a notice of quarantine treatment, and the owner or his agent shall, under the supervision of the customs, carry out disinfection, return or destruction. Those who pass the disinfection and disinfestation treatment are allowed to enter the country.

If it is necessary for the customs to issue a certificate for claim, the customs shall issue the relevant quarantine certificate in accordance with the regulations.

Article 26 the means of transport and containers for transporting imported Chinese herbal medicines shall meet the safety and health requirements. If it is necessary to carry out epidemic prevention and disinfection, it shall be carried out under the supervision of the Customs at the port of entry. Without the permission of the customs, no inbound Chinese herbal medicines may be unloaded from the means of transport, containers or transported.

Article 27 domestic shippers or their agents shall establish a record system for the import, sale and processing of Chinese herbal medicines, and keep relevant records for at least two years. At the same time, it should be equipped with safety management personnel for epidemic prevention of traditional Chinese medicine and establish a management system for epidemic prevention of traditional Chinese medicine.

Chapter III exit quarantine supervision

Article 28 Chinese medicinal materials leaving the country shall comply with the quarantine agreement, protocol, memorandum and other provisions signed between the Chinese government and the importing country or region, as well as the standards or contract requirements of the importing country or region.

Article 29 an outbound production enterprise shall meet the relevant requirements of the laws and regulations of the importing country or region and comply with the relevant laws and regulations of China.

Article 30 exit production enterprises shall establish a sound epidemic prevention system and traceability management system.

Outbound production enterprises shall establish purchase, acceptance records, production and processing records, ex factory inspection records, warehousing records, etc. of raw materials, packaging materials, etc., and record in detail the epidemic prevention management and product traceability throughout the production and processing of outbound traditional Chinese medicinal materials.

The above records shall be true and the retention period shall not be less than 2 years.

The exit production enterprise shall be equipped with quarantine management personnel, and the person responsible for epidemic prevention shall be clearly defined.

Article 31 Where the importing country or region requires the registration of the outbound production enterprises that export traditional Chinese medicinal materials to it, the customs shall implement registration. The registration is valid for 4 years.

Article 32 when applying for registration, an outbound production enterprise shall submit the following materials:

（1） Application form for Quarantine Registration of enterprises producing Chinese medicinal materials for exit;

（2） Plan of the plant area, and provide photos or video materials of key areas;

（3） Product processing technology.

Article 33 The customs directly under the jurisdiction of the locality shall deal with the applications of exit production enterprises respectively according to the following circumstances:

（1） If the application materials are complete and conform to the legal form, or the applicant submits all the supplementary and corrected application materials as required, the application shall be accepted;

（2） If there are errors in the application materials that can be corrected on the spot, the applicant shall be allowed to correct them on the spot;

（3） If the application materials are incomplete or do not conform to the legal form, the applicant shall be informed of all the contents that need to be supplemented and corrected on the spot or within 5 working days at a time. If the applicant fails to inform within the time limit, it shall be accepted from the date of receiving the application materials.

When accepting or rejecting an application, the customs directly under the customs shall issue a written certificate with the special seal of the administrative organ and a date.

Article 34 The customs directly under the central government shall, after accepting the application, form an evaluation team to conduct on-site evaluation of the outbound production enterprises that have submitted the application. The review team shall submit the review report to the customs directly under it in time after the on-site review.

Article 35 The customs directly under the central government shall, within 20 days from the date of accepting the application, make a decision on whether to approve the registration of the applicant's application; If registration is approved, a registration certificate shall be issued.

If the customs directly under the central government is unable to make a decision within 20 days from the date of accepting the application, it may extend the period by 10 days with the approval of the person in charge of the customs directly under the central government, and shall inform the applicant of the reasons for the extension.

Article 36 If the registered outbound production enterprise changes its name, legal representative, product type, storage, production and processing capacity, it shall submit a written application to the customs directly under it within 30 days after the change, fill in the application form for Quarantine Registration of outbound Chinese herbal medicine production enterprises, and submit materials related to the change.

If the enterprise name or legal representative is changed, the customs directly under the customs shall directly go through the change procedures after reviewing the relevant materials.

If the product type or production capacity is changed, the customs directly under the central government shall review the relevant materials and organize on-site review. After the review is qualified, the change procedures shall be handled.

If an enterprise relocates, it shall re apply to the customs directly under it for registration.

Article 37 Where it is necessary to recommend registration abroad, the customs directly under the General Administration of Customs shall submit the list of outbound production enterprises that have passed the preliminary examination to the General Administration of customs. The General Administration of Customs shall organize the evaluation, uniformly recommend to the competent departments of the importing countries or regions and handle the relevant procedures.

Article 38 the consignors or their agents of Chinese herbal medicines leaving the country shall apply to the customs of the place where the Chinese herbal medicine production enterprise is located for inspection. When applying for inspection, they shall truthfully declare the intended use of the products and submit the following materials:

（1） Contract, invoice and packing list;

（2） Factory certificate issued by the manufacturer;

（3） A written statement that the product meets the animal and plant quarantine requirements of the entering country or region.

Article 39 The Customs shall, in accordance with the provisions of Article 28 of these measures, exercise quarantine supervision over the exit Chinese herbal medicines.

The customs shall issue relevant quarantine certificates in accordance with regulations and allow the exit of Chinese herbal medicines that have passed the quarantine inspection or the disinfection and disinfestation treatment.

Those who fail to pass the quarantine inspection and have no effective methods for disinfection and disinfestation are not allowed to leave the country.

Article 40 the customs may, according to the relevant requirements of the General Administration of customs, implement classified management on the outbound Chinese herbal medicines and production enterprises under its jurisdiction on the basis of risk analysis, in combination with the outbound situation of Chinese herbal medicines, the requirements of importing countries or regions, the management ability and level of production enterprises, the integrity of production enterprises, and risk monitoring and other factors.

Chapter IV Supervision and Administration

Article 41 The Customs shall exercise quarantine supervision over the production, processing and storage of inbound and outbound Chinese medicinal materials.

Article 42 The General Administration of Customs shall monitor the epidemic situation of animal and plant epidemics of imported and exported Chinese medicinal materials.

When the competent customs finds problems in the monitoring, it shall handle and report them in time according to the regulations.

Article 43 the consignors or their agents of imported traditional Chinese medicinal materials and the manufacturers of outbound traditional Chinese medicinal materials shall establish an epidemic information reporting system and an emergency response plan. In case of finding epidemic information, it shall report to the customs in time and actively cooperate with the customs in dealing with the epidemic.

Article 44 The General Administration of Customs shall, based on the obtained risk information and risk analysis, issue a risk early warning information circular and decide to take the following control measures for relevant products:

（1） Conditionally restrict entry or exit, including strict monitoring and quarantine;

（2） It is forbidden to enter or leave the country, destroy it on the spot or return it;

（3） Revoke the registration qualification of the production enterprise;

（4） Start relevant emergency response plans.

The competent customs is responsible for organizing and implementing risk early warning and control measures.

Article 45 The General Administration of Customs may, with reference to the prevailing international practices, directly issue risk early warning notices for uncertain risks and take the control measures specified in Article 44 of these measures. At the same time, collect and supplement relevant information and data in time for risk analysis.

Article 46 when the epidemic risk of inbound and outbound Chinese herbal medicines has been eliminated or reduced to an acceptable level, the General Administration of Customs shall timely remove the risk early warning notice or risk early warning notice and control measures.

Article 47 the customs shall handle the epidemic situation found in the entry and exit quarantine of Chinese herbal medicines, especially the major epidemic situation, in accordance with the emergency response plan for the major animal and plant epidemic situation at the entry and exit.

Article 48 the customs shall bring the owners or their agents of imported and exported Chinese herbal medicines and domestic and foreign production enterprises under the management of good faith.

Chapter V Legal Liability

Article 49 If the owner or his agent of inbound and outbound Chinese medicinal materials commits one of the following illegal acts, the customs shall punish him in accordance with Article 40 of the animal and plant quarantine law of the people's Republic of China and Article

59 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

（1） Failing to apply for inspection or go through quarantine examination and approval procedures according to law, or failing to implement the provisions of quarantine examination and approval;

（2） The Chinese medicinal materials applied for inspection are inconsistent with the actual situation.

Article 50 the customs shall punish any of the following illegal acts in accordance with the provisions of Article 60 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

（1） Unloading or delivering imported Chinese medicinal materials from the means of transport without Customs permission;

（2） Opening or damaging animal and plant quarantine seals or signs without authorization.

Article 51 anyone who commits one of the following illegal acts shall be investigated for criminal responsibility according to law; If the case does not constitute a crime or the circumstances of the crime are obviously minor and do not require criminal punishment according to law, the customs shall punish it in accordance with Article 62 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

（1） Causing major animal and plant epidemics;

（2） Forging or altering inspection and quarantine documents, seals, marks and seals.

Article 52 any customs staff member who abuses his power in the implementation of quarantine and supervision and administration of inbound and outbound Chinese medicinal materials, deliberately creates difficulties for the parties, engages in malpractices for personal gain, forges inspection and quarantine results, or neglects his duty and delays the issuance of inspection and quarantine certificates shall be given administrative sanctions according to law; If a crime is constituted, criminal responsibility shall be investigated according to law.

Chapter VI supplementary provisions

Article 53 inbound and outbound Chinese medicinal materials involving wild or endangered protected animals and plants shall meet the requirements of relevant laws and regulations of China or relevant countries or regions.

Article 54 the entry and exit of traditional Chinese medicinal materials by international express delivery, mailing and passenger carrying shall comply with the relevant provisions.

Article 55 the quarantine of transit Chinese medicinal materials shall be handled in accordance with the law of the people's Republic of China on the entry and exit animal and plant quarantine and its implementation regulations.

Article 56 The General Administration of customs is responsible for the interpretation of these measures.

Article 57 these Measures shall enter into force as of December 1st, 2015.

Measures for the Administration of Imported Medicinal Materials

Promulgation date	2019/05/16	Effective region	NATIONAL
Promulgator	State Administration for Market Regulation	Document no	Order of the State Administration for Market Regulation No. 9
Effectiveness	Effective	Effective date	2020/01/01
Category	Pharmaceutical (Medical Treatment & Health Law->Pharmaceutical) ,Import & Export (Trade Law->Import & Export)		

Measures for the Administration of Imported Medicinal Materials

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.

ANNEXURE IV

Analysis of quarantine of imported Chinese medicinal materials

Chinese medicinal materials refer to the medicinal parts of plants and animals, which are formed by primary processing after harvest. According to the measures for the quarantine supervision and administration of imported and exported Chinese medicinal materials, the General Administration of Customs implements a use declaration system for imported Chinese medicinal materials. When Chinese herbal medicines enter the country, the enterprise shall declare the intended use to the competent customs to clarify whether they are used for medicine or for consumption. Chinese medicinal materials declared for medicinal use shall be articles listed in the catalogue of medicinal materials in the Pharmacopoeia of the people's Republic of China; Chinese medicinal materials declared for consumption shall be articles that can be used for food according to national laws, administrative regulations, rules and documents.

Qualification management of imported Chinese medicinal materials implemented by the customs

The General Administration of Customs implements risk management on imported Chinese medicinal materials. Implement registration management for overseas production, processing and storage units (hereinafter referred to as "overseas production enterprises") that export Chinese herbal medicines to China; Implement integrity management for enterprises engaged in the production and management of imported Chinese medicinal materials.

Quarantine requirements

The General Administration of Customs implements a quarantine access system for imported Chinese medicinal materials, including product risk analysis, evaluation and review of the regulatory system, determination of quarantine requirements, registration of overseas production enterprises, and entry quarantine.

The General Administration of Customs will conduct product risk analysis and regulatory system assessment for countries or regions that export Chinese herbal medicines to China for the first time, and conduct a retrospective review of countries and regions that have already traded.

According to the results of the risk analysis, the General Administration of Customs determines the catalogue of Chinese herbal medicines that need to be registered by overseas production, processing and storage units, and implements dynamic adjustment. The registration review procedures and technical requirements shall be separately formulated and issued by the General Administration of customs. The General Administration of Customs implements the registration of overseas production enterprises of traditional Chinese medicine listed in the catalogue, and the registration is valid for 4 years.

Registration process of overseas production enterprises

When applying for registration in China, the competent authorities of the exporting country or region must review the overseas production enterprises, and recommend them to the General Administration of Customs after meeting the relevant provisions of Articles 10 and 11 of the measures for the quarantine supervision and administration of imported and exported Chinese herbal medicines, and submit the following materials in Chinese or both Chinese and English:

animal and plant epidemics, veterinary health, public health, plant protection Laws and regulations on the registration management of enterprises, written materials on the institutional setup and personnel of the competent departments in the country or region where they are located, and the implementation of laws and regulations; List of overseas production enterprises applying for registration; The assessment conclusion of the competent department of the country or region where it is located on the actual situation of epidemic prevention and health control of the enterprise it recommends; A statement that the enterprise recommended by the competent department of the country or region where it is located meets the requirements of Chinese laws and regulations; Application for enterprise registration, plan of factory, workshop and warehouse, process flow diagram, animal or plant quarantine prevention and control system documents, photos of epidemic prevention and disinfection treatment facilities, photos of harmless treatment facilities of waste and packaging, etc.

After receiving the recommended materials and passing the written examination, the General Administration of Customs may, after consultation with the competent authorities of the exporting country or region, send personnel to the exporting country or region to evaluate its supervision system and inspect the overseas production enterprises applying for registration. The applicant enterprises that meet the requirements after inspection shall be registered.

For overseas production enterprises that have obtained registration and need to be renewed, the competent department of the exporting country or region shall apply to the General Administration of Customs six months before the expiration of the term of validity. The General Administration of Customs may send personnel to the exporting country or region to review its supervision system and inspect the overseas production enterprises that apply for it.

For countries or regions that meet the requirements in the retrospective review, overseas production enterprises that meet the requirements after inspection shall be registered, and the period of validity shall be extended for 4 years.

Declaration process

Before or at the time of entry of Chinese herbal medicines, the owner or his agent shall declare to the Customs at the port of entry with the following materials: quarantine certificate, certificate of origin, trade contract, bill of lading, packing list and invoice issued by the official of the exporting country or region and meeting the requirements of the General Administration of customs.

The customs shall examine the relevant documents submitted by the owner or his agent, and accept them if they meet the requirements.

If there is no valid quarantine certificate issued by the animal and plant quarantine institution of the government of the exporting country or region, registration is required, registration is not handled as required, or quarantine approval procedures are not handled according to law, the customs may return or destroy them according to the specific circumstances.

It should be noted that if the imported Chinese medicinal materials need to be approved for entry animal and plant quarantine, the owner or his agent should obtain the entry animal and Plant Quarantine License of the people's Republic of China in accordance with the provisions of the administrative measures for the approval of entry animal and plant quarantine before signing the trade contract.

On site quarantine content

The Customs at the port of entry shall carry out on-site quarantine in accordance with the following provisions:

Check the departure time and port, countries or regions passing through, loading list, etc., and check whether the documents are true and valid, and whether the documents are consistent with the name, quantity / weight, exporting country or region, shipping mark, mark, name of overseas production enterprise, registration number, etc.

Whether the package is in good condition, whether it has animal and plant packaging and bedding materials, and whether it complies with the provisions of the law of the people's Republic of China on entry and exit animal and plant quarantine and its implementation regulations, and the measures for the supervision and administration of the quarantine of wood packaging of imported goods.

Whether the traditional Chinese medicine has corruption and deterioration, whether it carries pests, animal excreta or other animal tissues, and whether it carries animal carcasses, soil and other prohibited substances.

Circumstances requiring quarantine treatment

In case of any of the following circumstances in the on-site inspection, the customs shall issue a notice of quarantine treatment and carry out corresponding quarantine treatment: those that are prohibited from entering the country by laws and regulations, those with prohibited objects, those whose cargo certificates are inconsistent, and those that are found to be seriously corrupt and deteriorated shall be returned or destroyed; If the package is damaged, the owner or his agent shall be responsible for sorting it out completely before unloading it from the means of transport; The customs shall carry out quarantine treatment on the contaminated sites, articles and instruments; Those with harmful organisms, animal excreta or other animal tissues shall be subject to quarantine treatment in accordance with relevant regulations; For those polluted by diseases and pests or suspected of being polluted by diseases and pests, the relevant goods shall be sealed up, and the contaminated goods, loading and unloading tools and sites shall be disinfected.

If diseases and pests or symptoms of diseases and pests are found during on-site quarantine, or laboratory quarantine is required according to relevant working procedures, the customs shall sample the imported Chinese herbal medicines and send them to the laboratory.

Before obtaining the quarantine certificate, Chinese herbal medicines should be stored in a place approved by the customs. Without the permission of the customs, no unit or individual may transfer, sell or process them without authorization.

The entry animal and Plant Quarantine License states that the product is subject to quarantine and processing supervision by the destination customs, and the port customs will issue an entry goods transfer notice after verification and inspection and external packaging disinfection. The consignee or his agent will apply to the destination customs for quarantine treatment within the specified time limit. Without quarantine inspection, it shall not be sold or processed.

Imported Chinese medicinal materials that need entry quarantine approval shall be stored and processed in the designated enterprises listed in the quarantine approval permit.

Issue quarantine certificate

The imported Chinese medicinal materials can be sold, used, stored and processed in designated enterprises only after they have passed the quarantine inspection and quarantine and the Customs has issued the inspection and quarantine certificate of the imported goods. The inspection and quarantine certificate of Inbound Goods shall list the name of the goods, country or region of origin, quantity / weight, production batch number / production date, purpose, etc.

If the goods fail to pass the quarantine inspection, the customs shall issue a notice of quarantine treatment, and the owner or his agent shall, under the supervision of the customs, carry out disinfestation, return or destruction. Those who pass the disinfestation treatment are allowed to enter the country.

If it is necessary for the customs to issue a certificate for claim, the customs shall issue the relevant quarantine certificate in accordance with the regulations.

Other requirements

Domestic shippers or their agents shall establish a record system for the import, sale and processing of traditional Chinese medicine, and keep relevant records for at least 2 years. At the same time, it should be equipped with safety management personnel for epidemic prevention of traditional Chinese medicine and establish a management system for epidemic prevention of traditional Chinese medicine.

The means of transport and containers for transporting imported Chinese herbal medicines shall meet the safety and health requirements. If it is necessary to carry out epidemic prevention and disinfection, it shall be carried out under the supervision of the Customs at the port of entry. Without the permission of the customs, no inbound Chinese herbal medicines may be unloaded from the means of transport, containers or transported.