Regulations for the Inspection and Examination of Imported Medicaments

(Amended Date:2015-07-03)

1.DOH Food No. 1021600820 Promulgated, May 13, 2013.
2.Article 24 and Annex II of Article 22 amended and promulgated by the Ministry of Health and Welfare Order Bu-Shou-Shi-Zi No. 1041603996 on July 3rd, 2015; for implementation from July 1st, 2015

Chapter I General Provisions

Article 1 These regulations have been established according to Paragraph 2 of Article 71-1 of the Pharmaceutical Affairs Act.

Article 2 Definition: terms used in these regulations:
1. Inspections: This refers to spot checks or examination before permitting the importation of medicaments
2. Examination: This refers to conducting sensory, chemical, biological, or physical tests in a laboratory.
3. Inspection authorities: This refers to inspection enforcement by the central competent health authority or its appointed agencies (organizations).
4. Obligatory inspection applicants: This refers to medicaments importers.

Chapter II Imported Drugs Inspection

Article 3 For drugs required for inspection by the competent authority , the obligatory inspection applicants shall submit the following documents to the inspection authority to carry out the inspection:
1. An application form for inspection.

2. A copy of medicaments permit license.
3. A copy of application for import declaration.
4. Necessary documents required by the central competent authority.
The application of the preceding paragraph can be submitted electronically.
Drugs pursuant to the first Paragragh that conform to one of the following situations can be exempted from inspection:
1. Products to be imported are issued with a certificate of examination by the government of the country of origin who has signed an examination waiver reciprocity agreement with the government of the Republic of China.
2. A special permit from central competent health authority granted for national emergency situation or to improve the public welfare.

Article 4 In addition to documentation review (as prescribed in Article 3), inspection authority can carry out the inspection of drugs in one or some of the following measures:
1. Batch-by-batch examination: carried out for each submitted batch of drugs.
2. Randomly-selected batch examination: performed based on a 2%-50% inspection rate.
3. On-site inspection: inspecting and checking (hereinafter referred to as ‘verification’) of items, packaging, appearance and labels of products on site.

Article 5 Reference standard and methods for the examination of imported drugs should abide to those mentioned in the Chinese Pharmacopoeia, pharmacopoeias published in the A10 countries or otherwise publicly announced by the central health competent authority.

Chapter III Imported Chinese medicine materials inspection

Article 6 Imported Chinese medicine materials shall not change the form of original material or tablets ready for decoction ,and the labels or packages shall indicate name of the medicament , lot number, name and address of the pharmaceutical firms. Reference standard and methods for the examination of imported Chinese medicine materials should abide to those mentioned in the Chinese Pharmacopoeia, pharmacopoeias published in Taiwan Herbal Pharmacopeia or otherwise publicly announced by the central health competent authority.

Article 7 For the Chinese medicine materials required for inspection by the competent authority, the obligatory inspection applicants shall submit the following documents to the inspection authority to carry out the inspection:
1. An application form for inspection.
2. A copy of Chinese medicines pharmaceutical firms permit license.
3. A copy of application for import declaration.
4. A certificate of examination issued by the laboratories approved by central health competent authority, Chinese medicine manufacturers in compliance with Pharmaceutical Good Manufacturing Practice Regulations, or related competent authority from the country of origin.
5. Necessary documents required by the competent authority.
The application of the preceding paragraph can be submitted electronically.

Chinese medicine materials that conform to one of the following situations can be exempted from inspection:

1. Products to be imported are issued with a certificate of examination by the government of the country of origin who has signed an inspection waiver reciprocity agreement with the government of the Republic of China.
2. The samples are permitted to import by the central competent health authority for the certificate of inspection pursuant to the fourth sub-paragraph of the first paragraph.
3. A special permit from central competent health authority granted for national emergency situation or to improve the public welfare.

Article 8 In addition to documentation review (as prescribed in Article7), inspection authority can carry out the Chinese medicine materials inspection in one or some of the following measures:

1. Batch-by-batch examination: The inspection is carried out for each submitted batch of Chinese medicine materials.
2. Randomly-selected batch examination: The inspection is performed based on a 2%-50% inspection rate.
3. On-site inspection: verification of items, packaging, appearance and labels of products on site.

Article 9 If any violation of Article 6 is found during the on-site inspection for the Chinese medicine materials , a notice shall be given by inspection authorities and the obligatory inspection applicants shall make correction within a prescribed time period; and submit to recheck afterwards.

Chapter IV Imported medical devices inspection

Article 10 For the medical devices required for inspection by the competent authority , the obligatory inspection applicants shall submit the following documents to the inspection authority to carry out the inspection:
1. An application form for inspection.
2. A copy of medical devices permit license.
3. A copy of application for import declaration.
4. Necessary documents required by the competent authority.
The application of the preceding paragraph can be submitted electronically.
Medical devices that conform to one of the following situations can be exempted from inspection:
1. Products to be imported are issued with a certificate of examination by the government of the country of origin who has signed an inspection waiver reciprocity agreement with the government of the Republic of China.
2. A special permit from central competent health authority granted for national emergency situation or to improve the public welfare.

Article 11 In addition to documentation review (as prescribed in Article9), inspection authority can carry out the medical devices inspection in one or some of the following measures:
1. Batch-by-batch examination: The inspection is carried out for each submitted batch of medical devices.
2. Randomly-selected batch examination: The inspection is performed based on a 2%-50% inspection rate.
3. On-site inspection: verification of items,

packaging, appearance and labels of products on site.
The methods for inspection and the items and methodologies for examination of imported medical devices as prescribed in Annex I.

File Annex I；The inspection methods andexamination methodologies, items and scope to be checked of imported medical devices.doc

Chapter V Others

Article 12 In the event the medicaments applied for inspection correspond to one of the following situations, the competent authority may require the obligatory inspection applicant to provide written documentation before a given date, to explain the reasons for non-conformance, and a proposed improvement plan with preventative measures:
1. Same product applied for batch-by-batch examination by the same obligatory examination applicant does not conform to regulations for the second time.
2. Products belong to the same origin of medicaments permit license, and whose inspection results do not conform to regulations for three times within 180 days.
3. Chinese medicine materials belonging to the same origin, same country and same commodity classification code of the Republic of China, and whose inspection results do not conform to regulations for three times within 180 days.

Article 13 In the event the medicaments applied for inspection correspond to one of the following situations, the competent authority may

temporarily suspend the application for inspection from the same manufacturer, same origin, or same country:
1. Products mentioned in the preceding article and the written documentations provided are not approved upon review.
2. Products mentioned in the preceding article requiring written documentations are not provided before the given date or the following imported products applied for inspection still do not conform to regulations by the given date.

Article 14 The obligatory inspection applicant shall file an application to the inspection authority at the port where the medicaments are to be imported, 15 days prior to the date of inspection.
If the representative files the application, an identification document for the representative shall be provided. The representative shall submit a letter of Power of Attorney and shall register at the inspection authority.

Article 15 The samples required for inspection shall be taken free-of-charge. The maximum number (amount) of sampling shall be limited to what is required for laboratory examination and sample retention purposes. After collecting the samples, the authority shall issue a receipt for sampling to customs officials and the obligatory inspection applicant.

Article 16 Inspectors shall conduct random sampling at port. If samples are difficult to be sampled at the port, the inspection authority shall designate an alternative sampling location.
For the above mentioned sampling, the obligatory inspection applicant shall not designate the sample.

Article 17 Examination shall be conducted in the order of sampling. However, the examination laboratory shall prioritize inspection on products applying for re-examination according to these regulations.

Article 18 For inspection of medicaments, that are difficult to sample in a container yard, require five or more days for examination at the laboratory, perishable, or lack stability on safety efficacy, the inspection authority shall issue a Notice of Prior for Import for custom clearance after the obligatory inspection applicant declares to bear the responsibility for the safety and storage of products imported with an Affidavit. The inspection authority may issue a Notice of Prior Release for Import for customs clearance since the necessity of examination.
If the pledged storage location does not conform to the actual storage location, or medicaments are put to use before receiving the import permit, the inspection authority may temporarily suspend acceptance of an application for prior release of imports by the obligatory inspection applicant for a period of 180 days.

Article 19 After medicaments applied for inspection are found to conform to the regulations, the inspection authority shall issue a medicaments import notification ,the obligatory inspection applicant can apply to the inspection authority for a notification of the medicaments import admitted.
The obligatory inspection applicant can claim remaining samples by presenting the sampling receipt within 15 days after receipt of the notice of inspection results. However, if the sample is not collected within the time period or has short shelf life, the inspection authority may dispose of the

samples directly.

Article 20 In the event the medicaments fail to conform to regulations, a notification of noncompliance for medicaments will be issued.
The obligatory inspection applicant can apply for re-examination to the original inspection authority within 15 days after receipt of the notification of results. Applications for re-examination is limited to one time only, and are performed by the original testing laboratory using remaining samples for the re-testing. For medical devices, if the remaining samples are not adequate for re-examination, additional sampling may be done according to Article 15.
Remaining samples of products that do not conform to regulations shall be destroyed after the end of the period of application for re-examination, unless otherwise stated by law.

Article 21 For imported medicaments that do not conform to regulations upon inspection, unless otherwise stated by law, shall be shipped back or destroyed by the obligatory inspection applicant.
If imported products that have been released via a prior release notice do not conform to regulations mentioned in the preceding paragraph, the competent authority shall order the obligatory inspection applicant to retrieve the medicaments, and ship back or destroy the medicaments according to the preceding paragraph.

Chapter VI Statutory Fees

Article 22 The statutory fees for Inspection of Imported Medicaments shall include the following:

1. Review fees;
2. On-site inspection fees;
3. Certificate fees;
4. Examination fees;

The inspection fees in the preceding paragraph is described in Annex II.

File Annex II.doc

Chapter VII Supplementary Provisions

Article 23 When conducting on-site inspections according to these regulations, inspectors shall carry their identification documents with them.

Article 24 These regulations shall be implemented on the date of promulgation.

The amendment to Annex II of Article 22 promulgated on July 3rd, 2015 shall be implemented from July 1st, 2015.