Regulations for the Inspection and Examination of Imported Medicaments
(Amended text highlighted in yellow)

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 or import certificate issued by the central competent health authority.
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 4-1 For active pharmaceutical ingredients (as raw materials in Article 16 of Pharmaceutical Affairs Act) that belong to classification codes in Chapters 28 and 29 of the Import and Export Commodity Classification of the Republic of China, management of randomly-selected batch examination in Subparagraph 2 of the foregoing article are as follows:

1. For those randomly-selected:

(1) Testing is done through rapid test instruments. Once determined as illicit drugs, they are to be forwarded to the customs or judicial/police authority for investigation.

(2) When test results cannot be determined or it is impossible to perform testing with rapid testing instruments, they shall be sealed immediately and may not be unpacked without authorization.

(3) For drugs that are sealed according to preceding item, the inspection authority may issue the notice allowing prior release of imported drugs to facilitate customs declaration after the applicant has prepared the affidavit as required by Article 18 and enclosed supporting documents for compliance of the storage site with the Regulations for Good Manufacturing Practice or having filed for reference with the competent municipal and county (city) health authority. The storage site, without prior approval

from the inspection authority, may not be changed unilaterally.

(4) The applicant indicated in the preceding item shall proactively notify the inspection authority for sending staff to the location compliance with the Pharmaceutical Good Manufacturing Practice Regulations for unsealing and examination. Those having met requirements shall be managed according to Article 19.

(5) The quantities involved in the randomly-selected batch examination are indicated in Annex 1.

2. For batches not being selected, the inspection authority will review the application documents. Those having met requirements shall be managed according to Article 19.

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 Article 9), 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 II.

Annex II：Theinspection 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 III.

Annex III.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.

Annex I

Quantities of APIs in random batch inspection	One piece is to be randomly inspected when the total number of pieces is within 50; two when it is between 51 and 100; three when it is between 101 and 500; four when it is between 501 and 1000; and five when it is more than 1,000.

Annex II: The inspection methods and examination methodologies, items and scope to be checked of imported medical devices

Item: Condom

CCC Code	Codes of classification	Item	
4014,10.00.10； 4014,10.00.90	L5300； L5310	Condom; Condom with spermicidal lubricant	1. Inspection methods and frequency： Condoms with the same obligatory inspection applicant, same items, same manufacturing brand, same origin, same type, same thickness or specification are subjected to batch-by-batch examination. For first inspection submission, randomly-selected batch inspection shall apply for those require compliance for3 consecutive batches. For one out of three batches will be randomly selected. Randomly selected, batch shall be for examined, while those not randomly-selected are subjected to on-site inspection. If non-conformities are found during the randomly-selected batch inspection process, the originally announced procedure of 3 consecutive batch examination shall be applied before permitted for randomly-selected inspecting require. 2. On-site inspection: Items to be inspected: packaging, appearance and labels of products including: name of the product, name and address of the manufacturer, date of manufacture or batch number, or expiry date. 3. Examination items: Randomly selected 315 samples per batch of 500,000 or below, and 500 samples per batch of 500,001 or above.

The ratio of Acceptable Quality Level (AQL) in accordance to ISO 2859-1, and the following test items are as follows according to Chinese National Standards (CNS) 6629 T2008 Standard of latex condom.

Items	Testing Levels	Acceptable Quality Level(AQL)
Appearance	Normal test I(at least for the sample code M)	0.4
Pin-hole test	Normal test I(at least for the sample code M)	0.25
Labeling	Must fully comply with all requiring	

Note: Minimum package shall label in Chinese for the following items: name of the product, date of manufacture or batch number, expiry date, and name and address of the manufacturer(import manufacturer may label in foreign languages), Medical device permit number and the importer. Single unit shall at least label date of manufacture or batch number ,name of the manufacture or brand(imported excluded) ,expiry date, and period of validity or shelf-life(limited in product with manufacturing date)in Chinese .For expiry date of the same series of mixed packaging, shall be based on the contents of a single package on the earliest date .

4. If re-examination is required, resampling shall be proceeded according to the abovementioned requirements.

Annex III

Item	The level of fees（NT $ ）
1. Inspection fees	Inspection fees shall be calculated based on CIF for the following rates: 1.For import Chinese medicine materials Fee rate: 0.15%,Minimum fee: NT$200,If the inspection fee is more than NT$100,000, the portion above NT$100,000 shall be collected at the rate of 0.075%. 2 For imported drug Fee rate: 0.25%,Minimum fee:NT$500,Iftheinspection fee is more than NT$100,000, the portion aboveNT$100,000 shall be collected at the rate of 0.125%. No inspection fee is required for active pharmaceutical ingredients. 3.For imported medical device Fee rate: 0.25%,Minimum fee: NT$500,If the inspection fee is more than NT$100,000, the portion above NT$100,000 shall be collected at the rate of 0.125%.
2.On-site fee	A NT$500 on-site fee for each person each time shall be collect during weekdays from 8:30 A.M. to 5:30 P.M. according to Government Agencies Working Calendar. The following extended operational hours ,an extra fee shall be collected 1.During weekday, from 6:00 AM to 8:30 AM or from 5:30 PM to 10:00 PM. An NT$400 fee for each batch of commodities shall be collected. 2. During weekends and statutory holidays shall be from 6:00 a.m. to 10:00 p.m.. An NT$1,000 fee for each batch of commodities shall be collected. 3. A fee of NT$2,000 shall be collected for activities taking place outside the operational hours mentioned in the preceding items 1) and 2). If the inspector cannot commute to the place of inspection and back within the same day, the on-site fees shall be collected in accordance with the costs and expenses set forth in the “Operating Guidelines Governing Domestic Business Travel Expenses”. No on-site fee is required for active pharmaceutical ingredients.

3.Certificate fee:		NT$100 shall be collected for each new, replacement or change permit items of certificate.	
4.Examination fee		Examination fee means fee for re-examination of import medicaments or whose examination results do not conform to randomly-selected batch examination and are back for batch-by-batch examination.	
Serial number	Examination items	Directions	Amount of fees collected
Chinese medicine materials			Fees are collected based on Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics.
A005	Heavy metal	By Colorimetric test method per item	
E011	Mercury		
E012	Arsenic		
E013	Lead		
E014	Copper		
E015	Cadmium		
E016	Organochlorine		
E017	Alfatoxins B1, B2, G1, G2		
Medical devices			
A001	General inspection (condom appearance)	Visual defects (serious or non-serious)	
B006	Condom：Pin hole test	According to CNS6629	

APIs			
A002	Identification	It is calculated by each component or in each method.	
Note: All fees are denominated in New Taiwan Dollar. Fees based on commodity prices that are denominated in foreign currencies shall be converted into New Taiwan Dollars, based on the exchange rates stipulated by the Customs Bureau and applicable for successive ten-day periods.			