Regulation on Management of Imported Drugs and Quasi-drugs

[Enforcement Date: 9/27/2020] [Ministry of Food and Drug Safety Notice No. 2020-82, 9/7/2020, Amendment of Other Act]

Ministry of Food and Drug Safety (Pharmaceutical Policy Division), 043-719-2608

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of this Decree is to ensure the quality of imported drugs and quasi-drugs and proper safety management by setting forth the details on customs clearance prediction report, preparation of import management documents, quality inspection bodies and testing laboratories, and quality inspection methods and procedures for imported drugs pursuant to Articles 42 (5) and (6), 43 (1), 69, and 73 of the 『Pharmaceutical Affairs Act』, Articles 60 and 85 (1) of the 『Regulation on Safety of Pharmaceuticals, etc.』, Article 51 of the 『Narcotics Control Act』, Article 20 of the Enforcement Decree thereof, Articles 27 and 39 of the 『Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biologics』, and Articles 22 and 25 of the 『Rules on the Safety and Support of Advanced Biologics』.

Article 2 (Scope)

This Decree shall apply to imported drugs (including oriental medicinal materials) and quasi-drugs pursuant to the provisions of Articles 42 (1) and 43 (1) of the 『Pharmaceutical Affairs Act』, Articles 4, 5, 57, 60, and 61 of the 『Regulation on Safety of Pharmaceuticals, etc.,』, Article 51 of the 『Narcotics Control Act』, Article 20 of the Enforcement Decree thereof, Article 27 (1) of the 『Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biologics』 and Articles 22, 24 and 25 of the 『Rules on the Safety and Support for Advanced Biologics』.

Chapter 2 Import management documents

Article 3 (Preparation of Import Management Documents)

The import management record shall state or include the following:

1. Product name
2. Deleted <8/23/2016>
3. Deleted <8/23/2016>
4. Deleted <8/23/2016>
5. Certificate of product authorization (notification)
6. Samples of the container, packaging and contents of attached documents
7. Deleted <8/23/2016>
8. Date of initial import (customs clearance)
9. Inspection body and testing laboratory report
10. Import (customs clearance) date and quantity by lot number
11. Quality inspection records falling under any of the following:
   a. Date and result of self-quality inspection by lot number
   b. Inspection body's inspection report by lot number
   c. Certificate of GMP compliance of a manufacturer and manufacturer's inspection report by lot number (limited to Article 5 (2) 2)
12. Date of sales and sales volume by vendor
13. Deleted <4/5/2013>

Chapter 3 Quality Inspection

Article 4 (Drugs under National Lot Release)

(1) Importers of drugs under national lot release shall submit a standard customs clearance prediction report through electronic data Interchange (hereinafter referred to as "EDI"), pursuant to the 『Electronic Trade Facilitation Act』, to the chairman of the Korea Pharmaceutical Traders Association before customs clearance and obtain authorization for national lot release by submitting an application for each lot number to the Minister of Ministry of Food and Drug Safety (hereinafter referred to as "the Minister") within 3 days of customs clearance. However, the scope of drugs exempt from authorization for national lot release shall comply with the provisions of the 『Regulations on the Designation, Authorization Procedure and Method of Drugs Subject to National Lot Release』 (Notification by the Ministry of Food and Drug Safety).

(2) The chairman of the KPTA shall transmit the submitted customs clearance prediction report to the head of the local regional office of the Ministry of Food and Drug Safety (hereinafter referred to as "head of the local regional office") using EDI.

Article 5 (Drugs other than Approved under National Lot Release)

(1) Importers of drugs or quasi-drugs (hereinafter referred to as "drugs") other than those approved under national lot release shall clear customs according to the following procedures:

1. Importers of drugs, excluding active pharmaceutical ingredients and oriental medicinal materials, shall submit a standard customs clearance prediction report using EDI, pursuant to the 『Electronic Trade Facilitation Act』, to the chairman of the KPTA before customs clearance and receive inspection by submitting a request for inspection to the head of the Public Health and Environment Research Institute in their respective city or province within 3 days of customs clearance. However, the heads of the PHERI in cities and provinces may request inspection to the director general of the National Institute of Food and Drug Safety Evaluation only for items for which inspection cannot be conducted by sending a statement of reasons for inability to test with the sample within 3 days from the date of receiving inspection request.
2. Importers of active pharmaceutical ingredients shall submit the standard customs clearance prediction report using EDI, pursuant to the 『Electronic Trade Facilitation Act』, to the chairman of the KPTA before customs clearance. However, raw materials that fall under Group 1 in Annex 8 of the 『Enforcement Decree of the Narcotics Control Act』 shall follow the authorization procedure in Article 20 of the Enforcement Decree thereof.
3. Importers of oriental medicinal materials shall submit an application for testing (including electronic documents; hereinafter the same shall apply) to the director general of the NIFDS, the head of the local regional offices of the MFDS, or the head of a MFDS-designated testing laboratory for each import, and go through customs clearance after the tests carried out s in accordance with inspection methods for imported oriental medicinal materials in Annex 1. However, if a certificate of sample collection (including electronic documents; hereinafter the same shall apply) under Article 6 (3) is issued and submitted to the head of the local regional customs office for in-depth testing and hazardous substances testing, customs clearance may be obtained first after sensory evaluation.

(2) Notwithstanding paragraph (1), drugs that fall under any of the following subparagraphs may be exempt from inspection or testing. However, in the case of subparagraph 6, only in-depth testing may not be required.

1. Orphan drugs
2. <Deleted.>
3. Drugs for which a quality control testing result certified by the government of the country of origin is submitted and confirmed by the head of a quality inspection body to meet the standards
4. Drugs that are re-imported by the same importer from the same manufacturer and that have already been inspected (however, oriental medicinal materials are excluded.)
5. Oriental medicinal materials imported by drug manufacturers (excluding medicinal herb

manufacturers) to manufacture drugs approved or notified pursuant to Article 31 of the Pharmaceutical Affairs Act (however, antlers, fresh antlers, antler slices, musk, ox bezoars, and eaglewood are excluded.)

6. Oriental medicinal materials imported by a medicinal herb manufacturer to manufacture drugs approved or notified pursuant to Article 31 of the Pharmaceutical Affairs Act (however, antlers, fresh antlers, antler slices, musk, ox bezoars, and eaglewood are excluded.)
7. Drugs for academic research, study, survey, clinical study, etc.
8. Drugs that have been determined appropriate based on the assessment of drug manufacturers' compliance with good manufacturing practices pursuant to Article 4 (1) 6 and 5 (2) of the 『Regulation on Safety of Pharmaceuticals, etc.』.

(3) The director general of the NIFDS, the heads of the regional offices of the MFDS, the heads of the PHERI in cities or provinces, or the head of an oriental medicinal materials testing laboratory designated by the MFDS (hereinafter referred to as "the head of a testing laboratory") that receive a request for inspection or an application for tests pursuant to paragraph (1) shall issue a receipt of application (including electronic documents). And in the case of receiving an application for testing of oriental medicinal materials, the details of the application shall be entered within one day from the date of receipt at the Pharmaceutical Information System of the MFDS (https://nedrug.mfds.go.kr).

Article 6 (Sealing)

(1) The minister, the director general of the NIFDS and the heads of the PHERI in cities or provinces conducting inspection or testing of drugs (excluding oriental medicinal materials) pursuant to Articles 4 and 5 shall direct related public officials to collect samples required for testing from the importer's warehouse and seal the remaining products.

(2) A public official from the NIFDS or regional offices of the MFDS, or a sensory inspector of the testing laboratories for oriental medicinal materials designated by the minister shall conduct a sensory evaluation on oriental medicinal materials that require in-depth testing and hazardous substances testing, collect a proper amount that is necessary from suitable oriental medicinal materials (for antlers take 3 and cut and collect 5 cm, for raw antlers take 3) in an appropriate container or packaging in a bonded area in the presence of the importer. When necessary, for example expensive oriental medicinal materials, the remaining products may be sealed. For fresh antlers, each specimen may be labelled with a necessary identifier at the bottom of it at the time of collection, so that the submitted samples after being dried may be confirmed as the same specimens.

(3) The sample collector shall issue a sample collection certificate containing product name, importer (company name, representative's name), country of origin, manufacturing date, expiration date, the number of specimens for testing, date and place of sample collection, sample collection volumes,

sample collector's name, attendees' names, and other necessary information to the importer. However, the sensory inspector shall deliver samples collected pursuant to paragraph (2) to the testing laboratory for oriental medicinal materials after sealing them.

(4) Importers shall not unseal or damage, sell/transfer or use drugs (including oriental medicinal materials) sealed without receiving conformity notification as a result of assay and test.

Article 7 (Notification of Quality Test Results)

(1) The Minister of MFDS and the head of a testing institution shall , upon request, conduct a quality testing of an imported drug product according to specifications and test methods stated in the certificate of import permit for the product unless otherwise specified for it, and determine whether the drug product meets quality standards. And the test results (certificate of laboratory testing) shall be immediately notified to the importer and the chairman of the KPTA.

(2) The director general of the NIFDS, the heads of the regional offices of the MFDS, and the head of a testing laboratory for oriental medicinal materials shall notify quality test results to the chairman of the KPTA and the importer. If the quality test result is appropriate, test certificate (including electronic documents) may be issued, upon request.

Article 8 (Report of Assay Results)

The heads of the PHERI in cities and provinces and the heads of oriental medicinal materials quality inspection bodies shall report the quality inspection results pursuant to Article 5 to the Minister of MFDS by the 10th of the month following the end of each half year.

Article 9 (Notification of Nonconforming Products)

The Minister of MFDS and the head of an inspection body shall immediately notify the head of the regional office with the jurisdiction over the importer's location of business, the head of the local customs office and the importer by providing a copy of the inspection report if there is a nonconforming product based on the result of the inspection pursuant to Articles 4, 5, and 7. However, in the case of oriental medicinal materials, the head of a quality inspection body for oriental medicinal materials shall also be notified immediately.

Article 10 (Management of Endangered Wild Animals and Plants)

(1) Anyone who intends to sell imported bear gallbladders or musk under the permission of the Minister of MFDS pursuant to Article 43 of the 『Pharmaceutical Affairs Act』 shall attach the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permit issued by the Minister of MFDS to each product by sales unit.

(2) Anyone who intends to affix the CITES permit pursuant to paragraph (1) shall submit an application in accordance with Annex 1 to the Minister, and the Minister shall review the application and issue a CITES permit according to Annex 2 when appropriate.

(3) The importer pursuant to the provisions of paragraph (1) shall prepare an import ledger containing information about product name, importer (company name, representative's name), import quantity, and other details and a sales ledger indicating the sales volume, sales amount, sales place and so on for the bear gallbladder or musk and maintain the documents for two years.

Article 11 (Re-review of Regulation)

Pursuant to Article 8 of the 『Framework Act on Administrative Regulations』 and the 『Regulations on the Issuance and Management of Directives and Established Rules』 (Presidential Decree No. 248), the appropriateness of this Decree every three years, counting from January 1, 2014 (referring to the period that ends on December 31 of every third year) shall be reviewed and proper measures including improvements shall be taken.

ADDENDUM <No. 2020-82, 9/7/2020>

Article 1 (Enforcement Date)

This notification will take effect on the date of its notification.

Article 2 Deleted.

Article 3 (Revision of Other Notices)

(1) Deleted

(2) Some of the Regulation on Control of Importation of Drugs and Quasi-drugs shall be amended as follows:

In Article 1, "Article 20" shall be replaced with "Article 20, Articles 27 and 39 of the 『Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biologics』, and Articles 22 and 25 of the『Rules on the Safety and Support of Advanced Biologics』.

In Article 2, Article 51 of the 『Narcotics Control Act』 and Article 20 of the Enforcement Decree thereof shall be replaced with Article 51 of the 『Narcotics Control Act』, Article 20 of the Enforcement Decree thereof, Article 27 (1) of the 『Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biologics』, and Articles 22, 24, and 25 of the 『Rules on the Safety and Support of Advanced Biologics』. From (3) to (6) are Deleted