Article Content

Title Regulations Governing the Trace and Track System for Medicinal Products Ch

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Category Ministry of Health and Welfare (衛生福利部)

Article 1 The Regulation is prescribed in accordance with Article 6.1.3 of the Pharmaceutical
Affairs Act (hereinafter referred to as “the Act”).

Article 2 The “Trace and Track System” stated in the Act 6.1.1 refers to distributors and manufacturers with the medicinal products which categorized and announced by the central competent health authority (hereinafter referred to as medicinal products), shall establish their own information system for tracing the source and tracking the flow of the medicinal products according to manufacturing, import, sale or export process and establish the information system and management measures.
The “Trace and Track System” stated in the Act 6.1.2 refers to the system established by central competent health authority in order to manage the system stated in the preceding paragraph.

Article 3 The regulation applies to the objects as follows:
1. The medicinal products license holders i.e. manufacturers or importers.
2. Other than the license holders, the distributors engaged in business of pharmaceutical wholesaling.

Article 4 The medicinal products license holders shall establish and declare the following information for their medicinal products :
1. Pharmaceutical manufacturing or importing information:
(1) Name of the medicinal product, approved number, indication, dosage form, ingredients, company name, name and address of manufacturer recorded on the medicinal product license.
(2) Bar code or other symbol for identification purpose.
(3) Batch number.
(4) Quantity.
(5) Manufacture date.
(6) Expiry date or shelf life.
(7) Declared import date of medicinal product.
2. The information of active ingredient:
(1) The source of active ingredient.
(2) Manufacturer's name, address and nationality.
3. Information regarding flow of medicinal product:
(1) Receptor’s name, address, contact person and telephone number.
(2) Name of medicinal product.
(3) Batch number.
(4) Quantity.
(5) Manufacture date.
(6) Expiry date or shelf life.
(7) Delivery date.
The license holders should submit all the trace and track information of previous month to the “Trace and Track System” in electronic form by 10th of each month.

Article 5 Distributors who engage in business of pharmaceutical wholesaling should establish and declare the following information for their medicinal products:
1. Information regarding product supplier:

(1) Name, address, contact person and telephone number of supplier.
(2) Name of the medicinal product and approved number on the medicinal product license.
(3) Batch number.
(4) Quantity.
(5) Manufacture date.
(6) Expiry date or shelf life.
(7) Delivery date.
2. Information regarding flow of medicinal product:
(1) Name, address, contact person and telephone number of receptor.
(2) Name of the medicinal product and product license number.
(3) Batch number.
(4) Quantity.
(5) Manufacture date.
(6) Expiry date or shelf life.
(7) Delivery date.
Distributors who engage in business of pharmaceutical wholesaling should submit all the trace and track information of previous month in electronic form by the 10th of each month.

Article 6 The manufacturers and distributors in the preceding two articles should keep vouchers, documents and data as evidence of the information in the preceding two articles for at least five years from the date of manufacturing, import, export or supply.

Article 7 The companies shall not evade, obstruct or refuse the request from the competent health authorities who are eligible to access data.

Article 8 The enforcement date of the regulations is stipulated by the central competent health authority.