



**Atthachai Homhuan**  
Manager, Regulatory Affairs  
atthachai.h@tilleke.com

## Electronic Data Linkage Between Thai FDA and Customs

**W**ith the ASEAN Economic Community (AEC) due to come into effect in 2015, Thailand has prioritized modernizing its customs procedures to better facilitate trade across international borders. The country is taking a step-by-step approach, with the first prototypical reforms taking root in the cosmetics industry. It is hoped that implementing a single-window system with online capabilities will improve efficiency by hastening trade processes and reducing associated costs.

### AEC and National Single Window

To comply with Thailand's AEC commitments, the country's Food and Drug Administration (FDA) has implemented both procedures to harmonize technical regulations and mutual recognition agreements to certify and test healthcare products. The aim of this harmonization scheme is to ensure the quality, safety, and efficacy of healthcare products for people in ASEAN.

In addition to the improvements made to technical regulations, Thailand has also made progress in developing its logistics infrastructure. As a signatory to the Agreement to Establish and Implement the ASEAN Single Window, Thailand has worked toward establishing the National Single Window (NSW) to reduce logistics costs, increase competitiveness, and support international trade for ASEAN integration. By providing a single-window system that allows international traders to submit trade-related documents at one clearly designated location, efficiency is greatly enhanced. The entire trade process becomes funneled through a single point of entry that fulfills all import, export, and transit regulatory requirements, and traders are no longer held back by lengthy dealings with government authorities. Not only does this save time and costs, but it facilitates the processing of data and information, which allows for easier decision making and faster response times when deliberating Customs release and cargo clearance.

### E-Logistics and License per Invoice

In implementing the NSW, the FDA and Customs Department have made two significant developments; they have prepared a product-information database and set up a platform of communications and data exchange between both agencies. Within the healthcare industry, the e-logistics system has been fully implemented for cosmetics, and it has proved to be a successful prototype.

Before registering a cosmetic product, a company must first register as an importer (or manufacturer) with the FDA and request an electronic activation code. After that, cosmetics can be registered online with the e-activation code specific to each company. After submission, the FDA will evaluate and approve the registration request with the same electronic system.

Once registration is approved, the company must log in to the e-logistics system and input the Customs tariff (Harmonized System or HS code) of the corresponding

products before importing cosmetics for sale. The company must also record the invoice number and keep a detailed description of the invoice and expected date of product shipment into Thailand. The importer must ensure that each item in the invoice has a corresponding product license number. This is the step where the invoice and product license are connected with each other.

Later, when the FDA officers at Customs or the embarking port log in to the e-logistics system, they can verify whether the products to be imported have valid licenses and check whether the product details and packing size are correct. This verification step is normally called "license per invoice." Provided there are no issues regarding the verification of license and invoice, the company can fast-forward the traditional cargo clearance with the Customs Department.

Because the company information, product information, registration license, Customs tariff, and detailed information provided in the invoice are already in the e-logistics system, product release and Customs clearance is better facilitated. Nevertheless, to safeguard the e-logistics system's benefits of importing healthcare products, importers should ensure:

- ▶ Their products are already registered with the FDA (with product license number);
- ▶ The product brand name and packing sizes shown on the invoice are in line with the information previously submitted to the FDA; and
- ▶ The invoice from the country of origin should be provided at least a couple of days before any shipment. This ensures the company has sufficient time to input the information into the system and the officer can verify the license per invoice before the goods arrive.

If certain items in the invoice do not have product license numbers, all products in that invoice can be detained or deported out of Thailand.

Currently, the e-logistics system is only operational for cosmetic products. For other healthcare products, manual registration of the product at the FDA is still required; for example, a medical device registration dossier must still be submitted to the FDA. The company must request an ID number, similar to an e-activation code for cosmetics. Once the product license is granted, the company will send a CD to the FDA containing an Excel template of their license per invoice. An FDA officer will verify the license per invoice and upload it to the NSW system, where there is linkage of information between the FDA and Customs Department.

### Benefits of Linkage

Data integration between FDA and Customs is an important step forward in enhancing Thailand's logistics management system. Companies can overcome bureaucratic hurdles and easily record information via the e-system, while the authorities use the system as a safeguard to ensure that imported products have already been approved and confirm that the Customs tariff declared by the company is in line with product classification. This results in a smoother process and quicker release of regulated products from Customs ports.

With the system now functioning well for cosmetics, companies can look forward to full implementation of their healthcare products in other sectors as well. The fully implemented system will greatly improve logistics efficiency in Thailand. To move ahead, the government will need to earmark sufficient funding to improve its IT infrastructure so it can handle a wider range of products. 🚚