COVUE

Quasi-drug Import in Japan

Quasi-drug products are regulated by the Ministry of Health, Labor, and Welfare (MHLW) in Japan.

First Shipment with COVUE

- Import Application (per shipment)
- Approval by MHLW (per shipment)
- One Application per Manufacturing Plant
- Up to 25 SKUs (per application)
- Average Approval Time: 180-270 days

Note:

- Only a Japanese company licensed for Import, Sales & Marketing of Quasi Drugs can legally import the product on behalf of the foreign seller.
- Whoever handles the Japan import application will control the product rights, regardless of the contractual agreement between the importer and the license holder.
- Regulated products cannot be shipped directly. They must arrive at the facility of the license holder where the products are registered.
- The products must undergo a compliance inspection for labeling and random lab testing.
- MHLW is the agency responsible for the regulation of quasi-drugs.

Why Choose COVUE?

Our license permits our clients omni-channel access to the Japanese market. Our Sales & Marketing license umbrellas all sellers and resellers in Japan.

We never lock your product rights under compliance. If at any time you wish to change, please contact us, and we will unregister your products.

Application Requirements:

- Ingredient list by percentage (in English)
- Lab testing of products
  (MHLW will determine the testing parameters during the application process)
- Product claims
- Manufacturing plant information
- Manufacturing flow process (if requested)
- Source of ingredients (if requested)

Steps

1. Submit your product information to COVUE compliance for pre-application review
2. Register your company under COVUE's license
3. Register your products with COVUE
4. Open an import application (notification) with the Ministry of Health, Labor, and Welfare (MHLW)
5. Product label creation and registration
6. Receive approval for import
7. Create a shipping invoice from the COVUE IOR account
8. Ship to COVUE for IQC inspection* (notification)
9. Ship to final destination

*Note: *Japan law requires all PMDA-regulated products to be received at the licensed IOR facility for IQC inspection. The process takes 48-72 hours.*

For more information, click here.

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