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New Regulations on Pharmaceutical Product Labeling in Vietnam

On January 18, 2018, the Ministry of Health (MoH) of Vietnam issued Circular No. 01/2018/TT-BYT (Circular 01) on the labeling of pharmaceuticals (referred to hereinafter as “drugs” for brevity). This circular will take effect from June 1, 2018, and will replace the current drug labeling regulations (Circular No. 06/2016/TT-BYT).

Circular 01 includes four chapters and 40 articles, providing guidelines on: (1) labels of finished product drugs and drug raw materials; (2) package inserts of finished drugs; and (3) changing the shelf life indicated on the label of finished drugs in special cases.

In light of the new circular, some notable changes will be forthcoming, including, among others:

Requirements for Package Inserts of Finished Drugs

Under current regulations, the package insert (PI) must include two separate sections, one with information for patients and the other with information for healthcare professionals. Under the new regulations, the PI will include only one section, containing general information for both patients and healthcare professionals. The simpler PI will reduce the time spent preparing the language for the PI and preparing packaging samples when registering drugs.

Package Insert Replacement after Finished Drug Is Imported into Vietnam

Under current regulations, a PI may not be replaced or supplemented after the finished drug is imported into Vietnam. Under the new Circular, this restriction is loosened,

and a PI can be replaced or supplemented in Vietnam in the following circumstances:

- ▶ When imported drugs with Marketing Authorization (MA) licenses have Vietnamese-language PIs in their packages but the PIs have not been updated per the MoH’s requirements; and
- ▶ When imported drugs with import licenses do not have Vietnamese-language PIs in their packages.

Entities in Charge of Imported Drug Labeling

The responsible entities for drug labeling have been changed under the new circular, effectively releasing offshore manufacturers from labeling responsibility.

- ▶ The responsible entities for a product with an MA license will be the importer and the MA holder. Currently, the responsible entities are the manufacturer and the MA holder.
- ▶ The responsible entity for a product with an import license will be the importer only. Currently, the responsible entities are the manufacturer and the importer.

Transitional Provisions

Circular 01 provides the following transitional provisions:

- ▶ Drugs granted registration numbers before June 1, 2018, may be sold with MoH-approved labels and PIs until the expiry date of the MA license.
- ▶ In the case of drugs for which the MA/import license dossiers were submitted to the DAV before June 1, 2018, and are awaiting the DAV’s approval, the following will apply:
 1. The applicant may submit updated labels and updated PIs for the drug in accordance with the new circular; or
 2. If no updated documents are submitted to the DAV, the applicant’s label and PI may be considered by the DAV under current regulations. However, within six months from the date on which an MA license is issued, the MA holder must submit updated labels and PI in the form of a variation registration to comply with Circular 01. Circular 01 is silent on the duty of the import license holder in this situation. 🚧