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Vietnam Pharma Update

Circular 44 Updates Drug Registration Requirements

To ensure harmony in regulations between ASEAN countries as well as tighten the management of drug registration, the Ministry of Health (MOH) issued Circular No. 44/2014/TT-BYT dated November 25, 2014, on Registration of Drugs (Circular 44) to replace its previous Circular No. 22/2009/TT-BYT (Circular 22) dated November 24, 2009. Circular 44 took effect on January 15, 2015. Among the contents of Circular 44, there are four main points changed from Circular 22:

1. New conditions for Marketing Authorization holders: Under Circular 22, if a foreign company wanted to become a Marketing Authorization (MA) holder for a drug, it had to register for and obtain a license for a foreign company operating in medicines and raw medicinal materials in Vietnam (Operating License). However, under Circular 44, a foreign company with a license to manufacture or trade in drugs in its original country and that has established a representative office in Vietnam can be an MA holder. The Operating License is no longer a prerequisite. If the foreign company does not have a representative office in Vietnam, then it must authorize a local company in Vietnam to be the MA holder.

2. Change of responsible authority for in vitro diagnostic biologicals: Under Circular 44, the Drug Administration of Vietnam (DAV) will no longer be responsible for evaluating application dossiers for in vitro diagnostic (IVD) biologicals. IVD biologicals are now managed by the Department of Medical Equipment and Health Works under the MOH. Required documents for the application dossier of IVD biologicals are regulated in Circular 44 in harmony with ASEAN Common Technical Documents (ACTD).

3. MA extensions permitted: Under Circular 22, when MAs (also known as visas) expired, the holders were required to submit renewal dossiers. Under Circular 44, for drugs that have been granted MAs for five years, have been marketed in Vietnam, and satisfy certain requirements, the MA holders can apply for extensions without renewal, which involves a simpler application dossier. Additionally, renewals can be submitted within 12 months prior to the expiry date of the visa, instead of 6 months as before.

4. Change of classification and requirements for post-approval variations: Under Circular 44, the list of notifications and post-approval variations (which include major, minor and other variations) has been updated in accordance with the latest version of ASEAN variation guidelines for pharmaceutical products. Under Circular 22, most changes to drug substances were classified as notifications, but now they are classified more strictly as minor and even major variations. ■

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