©2016 Tilleke & Gibbins International Ltd.

<< Left
Chuyen Hong Huu Le
Attorney-at-Law
chuyen.l@tilleke.com

<< Right
Kien Trung Trinh
Senior Attorney-at-Law
kien.tt@tilleke.com

Vietnam's New Pharmaceutical Law

The National Assembly of Vietnam adopted a new Law on Pharmacy on June 4, 2016. The new law will take effect on January 1, 2017, replacing the current version which was passed in 2005. In an effort to update certain aspects of Vietnam's legal framework to be more in line with international practices, the new pharmaceutical law is expected to provide quicker access to drugs for patients, increased consumer protection, and more incentives for local manufacturing of drugs.

Removing the Five-Year Rule for Clinical Trials

Under the Law on Pharmacy of 2005, which is currently in effect, before a new drug can be circulated in Vietnam, it must undergo clinical trials in Vietnam for registration purposes. The drug is only exempted from this requirement if it has already been circulated legally for at least five years in its country of origin. As a result, unless costly and cumbersome clinical trials are performed, Vietnamese patients have to wait at least five years to gain access to new drugs that have already been approved for circulation in other countries.

Under the new Law on Pharmacy, this barrier has been lifted. Accordingly, the clinical trial requirement would be waived for all new drugs, except vaccines, provided that they have sufficient clinical data on safety and efficiency and are circulated in at least one country anywhere in the world. With this change, Vietnamese patients will gain earlier access to new drugs, especially those that treat life-threatening diseases. Pharmaceutical companies will also benefit by not being forced to repeat clinical trials that have already been performed.

Expanding Retail of OTC Drugs

The new Law on Pharmacy allows certain non-prescription drugs, also known as over-the-counter (OTC) drugs, to be sold by a business establishment that does not have a certificate of eligibility for pharmaceutical business. These establishments include, among others, venues that have drug counters or cabinets, such as supermarkets.

Although the list of OTC drugs is not yet available and the relevant establishments still need to satisfy certain criteria on storage conditions and human resources, this is still a major change, as it appears likely to provide consumers with improved access to certain OTC drugs.

Acknowledging Patient Assistance Programs

Article 42 of the new law permits pharmaceutical companies to provide free drugs to health establishments through a patient assistance program. Previously, pharmaceutical companies always had to be concerned as to whether directly conducting such programs would be in breach of the law, as conducting promotional activities in relation to drugs targeting patients is prohibited in Vietnam.

Recognizing Clinical Pharmacology

The new Law on Pharmacy provides a separate chapter dedicated to clinical pharmacology, instead of scattered regulations as in the previous law. The purpose of this chapter is to ensure that drugs will be used in a reasonable, safe, and effective manner. While the contents of this chapter are cursory, its existence suggests that the government views clinical pharmacology and drug safety as an important issue.

Permitting Parallel Imports

The new Law on Pharmacy specifically allows parallel import of drugs as long as the price of the parallel-imported product is lower than the price of the original brand-name drug currently being circulated in Vietnam. Though the general concept of parallel imports is not new to the pharmaceutical industry in Vietnam, this is the first time that a regulation on parallel imports has been promulgated under a law.

Incentivizing Local Manufacturing

The new Law on Pharmacy clearly shows that national policy prioritizes the purchase of domestically produced products, including domestically manufactured generics and biosimilars, herbal and traditional medicines manufactured from domestic herbal ingredients, and drugs manufactured in domestic facilities meeting good manufacturing practice standards.

> "in an effort to update certain aspects of Vietnam's legal framework to be more in line with international practices, the new pharmaceutical law is expected to provide quicker access to drugs for patients, increased consumer protection, and more incentives for local manufacturing of drugs"

Moreover, the new law reflects a preferential treatment for domestically produced drugs over imported drugs that first appeared in the Law on Procurement. That is, when domestically produced drugs are available that satisfy the Ministry of Health's requirements on medical treatment, price, and supply, the dossier for a drug tender must stipulate that tenderers are not allowed to offer imported drugs. As a result of those regulations, there are more foreign pharmaceutical companies considering the option of going "local."

Summary

The new Law on Pharmacy represents a milestone achievement in healthcare in Vietnam and is likely to have a major impact on patients and pharmaceutical companies, with the key benefit for consumers being earlier access to pharmaceutical products, due to the removal of the clinical trial requirement. As the new Law on Pharmacy is of critical importance, the government will likely issue a large number of decrees and circulars that will guide the implementation of the new law when it takes effect next year.